

**CUMULATIVE  
SUPPLEMENT 4  
APRIL 2003**



**APPROVED  
DRUG PRODUCTS**

**WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**23<sup>rd</sup> EDITION**

**Department of Health and Human Services**

**Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Generic Drugs**

2003

HYMAN, PHELPS  
&MCNAMARA, P.C.  
WASHINGTON, DC

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**Cumulative Supplement 4**

**April 2003**

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**CUMULATIVE SUPPLEMENT 4**  
**April 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have never been marketed, are for exportation, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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)  
LEK SERVICES INC  
(LEK SVCS)  
LEK LJUBLJANA PHARMACEUTICAL AND CHEMICAL CO  
(LEK LJUBLJANA)  
LEK PHARMACEUTICAL AND CHEMICAL DD  
(LEK PHARM)

ROCHE PALO ALTO LLC  
(ROCHE PALO)  
LEK PHARMACEUTICALS DD  
(LEK PHARM DD)  
LEK PHARMACEUTICALS DD  
(LEK PHARM DD)  
LEK PHARMACEUTICALS DD  
(LEK PHARM DD)

1.3 NITROGLYCERIN, FILM, EXTENDED RELEASE; TRANSDERMAL 23<sup>RD</sup> ANNUAL EDITION

The *Approved Drug Products with Therapeutic Equivalence Evaluations 23<sup>rd</sup> annual edition*, page 3-265 omitted the 3 character Therapeutic Equivalence (TE) Codes for Nitroglycerin, Film, Extended Release; Transdermal products. The correct codes are listed below by product name, applicant holder, TE code, strength, NDA number, and product number.

<u>PRODUCT NAME</u>	<u>APPLICANT</u>	<u>TE CODE</u>	<u>STRENGTH</u>	<u>NDA</u>	<u>PRODUCT</u>
MINITRAN	3M	AB1	0.1MG/HR	N89771	001
MINITRAN	3M	AB1	0.2MG/HR	N89772	001
MINITRAN	3M	AB1	0.4MG/HR	N89773	001
MINITRAN	3M	AB1	0.6MG/HR	N89774	001
NITRO-DUR	KEY PHARMS	AB1	0.1MG/HR	N20145	001
NITRO-DUR	KEY PHARMS	AB1	0.2MG/HR	N20145	002
NITRO-DUR	KEY PHARMS	AB1	0.4MG/HR	N20145	004
NITRO-DUR	KEY PHARMS	AB1	0.6MG/HR	N20145	005
NITROGLYCERIN	HERCON LABS	AB2	0.2MG/HR	N89884	001
NITROGLYCERIN	HERCON LABS	AB2	0.4MG/HR	N89885	001
NITROGLYCERIN	HERCON LABS	AB2	0.6MG/HR	N89886	001
NITROGLYCERIN	MYLAN	AB2	0.1MG/HR	N75033	001
NITROGLYCERIN	MYLAN	AB2	0.2MG/HR	N74609	001
NITROGLYCERIN	MYLAN	AB2	0.4MG/HR	N74607	001

#### 1.4 AVAILABILITY OF THE EDITION

The 23rd 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>

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 2002) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

### DEFINITIONS

#### Drug Product

For this report, a drug product is the representation in the Prescription Drug Product List of an active moiety (molecular entity and its salts, esters and derivatives) either as a single ingredient or as a combination product provided in a specific dosage form and strength for a given route of administration with approval for marketing by a firm under a particular generic or trade name.

#### New Molecular Entity

A new molecular entity is considered an active moiety that has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or as part of a combination.

### REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

#### COUNTS CUMULATIVE BY QUARTER

<u>CATEGORIES COUNTED</u>	<u>DEC 2002</u>	<u>JUN 2003</u>	<u>SEP 2003</u>	<u>DEC 2003</u>
DRUG PRODUCTS LISTED	10465			
SINGLE SOURCE	2420 (23.1%)			
MULTISOURCE	7939 (75.9%)			
THERAPEUTICALLY	7659 (73.2%)			
EQUIVALENT				
NOT THERAPEUTICALLY	280 (2.7%)			
EQUIVALENT				
EXCEPTIONS <sup>1</sup>	106 (1.0%)			
NEW MOLECULAR ENTITIES	6			
APPROVED				
NUMBER OF APPLICANTS	598			

<sup>1</sup>Amino acid-containing products of varying composition (see Introduction, page xx of the List).

## 1.6 CUMULATIVE SUPPLEMENT LEGEND

The List is sorted by Ingredient(s) and, within each grouping, by the Dosage Form; Route and then by trade name.

The individual product record contains the Therapeutic Equivalence Code, Reference Listed Drug symbol, applicant holder, strength(s), New Drug Approval number, product number, and approval date. The last two columns describe the action. The Action Month is the CS month the action occurred. The OB Action is the type of change that has occurred.

New ingredient(s), new dosage form; route(s), new trade names, and new product additions are preceded by >A> during the action month. The change month is the current CS month; the change code for new approvals is NEWA. Following months will display the same information without the >A>.

Changes to currently listed products will list two records. The deleted product record will be preceded by >D>. The product record change addition being made will be preceded by >A>. Following months will display only the >A> record without the >A>. All changes that occur to the product through the Annual year will be listed. The change month and change code will document the change.

The change code and description:

NEWA	New drug product approval usually in the supplement month.
CAHN	Applicant holder firm name has changed.
CDFR	Change. Dosage Form; Route of Administration.
CFTG	Change. A first time generic for the innovator product. A TE Code is added.
CMFD	Change. The product is moved from the Discontinued Section due to a change in marketing status.
CMS1	Change. Miscellaneous addition to list.
CMS2	Change. Miscellaneous deletion from list.
CPOT	Change. Potency amount/unit.
CRLD	Change. Reference Listed Drug.
CTEC	Change. Therapeutic Equivalence Code.
CTNA	Change. Trade Name.
DISC	Discontinued. The Rx or OTC listed product is not being marketed and will be moved to the discontinued section in the next edition.
WDAG	Withdrawn. The applicant holder has notified the FDA in writing that the product is no longer being marketed resulting in the product approval being withdrawn by mutual agreement. The product will be listed in the Discontinued Section.
WDRP	Withdrawn. The application approval has been withdrawn for failure to provide Annual Reports. The product will be moved to the Discontinued Section in the next edition.

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

SOLUTION; ORAL

ACETAMINOPHEN AND BUTALBITAL AND CAFFEINE

+ MIKART 325MG/15ML;50MG/15ML;40MG/15ML N40387 001 JAN 31, 2003 JAN NEWA

TABLET; ORAL

FIORICET

>D> AB + NOVARTIS 325MG;50MG;40MG N88616 001 NOV 09, 1984 APR CAHN

>A> AB + WATSON PHARMS 325MG;50MG;40MG N88616 001 NOV 09, 1984 APR CAHN

ACETAMINOPHEN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE

CAPSULE; ORAL

FIORICET W/ CODEINE

AB + WATSON PHARMS 325MG;50MG;40MG;30MG N20232 001 JUL 30, 1992 MAR CAHN

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

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

+ ANDRX PHARMS 500MG;30MG N40441 001 MAR 27, 2003 MAR NEWA

+ 500MG;15MG N40447 001 FEB 26, 2003 FEB NEWA

+ 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

ACYCLOVIR

CAPSULE; ORAL

ACYCLOVIR

>A> AB AAIPHARMA 200MG N74833 001 APR 22, 1997 APR CAHN

>D> AB AESGEN 200MG N74833 001 APR 22, 1997 APR CAHN

ALBUTEROL SULFATE

SOLUTION; INHALATION

ALBUTEROL SULFATE

>A> AN NOVEX EQ 0.5% BASE N76391 001 APR 01, 2003 APR NEWA

ALFENTANIL HYDROCHLORIDE

INJECTABLE; INJECTION

ALFENTA

AP + AKORN EQ 0.5MG BASE/ML N19353 001 DEC 29, 1986 MAR CAHN

ALMOTRIPTAN MALATE

TABLET; ORAL

AXERT

>A>	JANSSEN ORTHO	EQ 6.25MG BASE	N21001 001	MAY 07, 2001	APR	CAHN
>A>	+	EQ 12.5MG BASE	N21001 002	MAY 07, 2001	APR	CAHN
>D>	PHARMACIA AND UPJOHN	EQ 6.25MG BASE	N21001 001	MAY 07, 2001	APR	CAHN
>D>	+	EQ 12.5MG BASE	N21001 002	MAY 07, 2001	APR	CAHN

ALPHA-TOCOPHEROL; ASCORBIC ACID; BIOTIN; CHOLECALCIFEROL; CYANOCOBALAMIN; FOLIC ACID;  
 NIACINAMIDE; PANTOTHENIC ACID; PYRIDOXINE; RIBOFLAVIN; THIAMINE; VITAMIN A

INJECTABLE; INJECTION

CERNEVIT-12

@ 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

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

AMANTADINE HYDROCHLORIDE

CAPSULE; ORAL

AMANTADINE HCL

>A>	AB	GENEVA PHARMS	100MG	N71293 001	FEB 18, 1987	APR	CAHN
>D>	AB	GENEVA PHARMS TECH	100MG	N71293 001	FEB 18, 1987	APR	CAHN

AMCINONIDE

CREAM; TOPICAL

>A>		AMCINONIDE					
>A>	AT	TARO PHARM INDS	0.1%	N76229 001	MAY 31, 2002	APR	NEWA
>D>	+	FUJISAWA HLTHCARE	0.1%	N18116 002		APR	CFTG
>A>	AT	+	0.1%	N18116 002		APR	CFTG

OINTMENT; TOPICAL

AMCINONIDE

AB	TARO PHARM INDS	0.1%	N76367 001	MAR 19, 2003	MAR	NEWA
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AMIODARONE HYDROCHLORIDE

INJECTABLE; INJECTION

AMIODARONE HCL

>A>	AP	APOTEX	50MG/ML	N76394 001	APR 25, 2003	APR	NEWA
	AP	+	CORDARONE				
		WYETH PHARMS INC	50MG/ML	N20377 001	AUG 03, 1995	MAR	CAHN
		TABLET; ORAL					
	AB	WYETH PHARMS INC	200MG	N18972 001	DEC 24, 1985	MAR	CAHN

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL

	ETRAFON 2-10					
	@ SCHERING	10MG;2MG		N14713 007		MAR DISC
	ETRAFON 2-25					
	@ SCHERING	25MG;2MG		N14713 004		MAR DISC
	ETRAFON-FORTE					
	@ SCHERING	25MG;4MG		N14713 006		MAR DISC

AMMONIUM LACTATE

CREAM; TOPICAL

AMMONIUM LACTATE

>A>	AB	TARO	EQ 12% BASE	N75883 001	APR 10, 2003	APR	NEWA
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AMOXICILLIN; CLAVULANATE POTASSIUM

FOR SUSPENSION; ORAL

AMOXICILLIN AND CLAVULANATE POTASSIUM

AB	RANBAXY	200MG/5ML;EQ 28.5MG BASE/5ML		N65132 001	MAR 19, 2003	MAR	NEWA
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						
+	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						
AB	SHIRE LABS	3.125MG;3.125MG;3.125MG;3.125MG		N11522 012	AUG 31, 2000	MAR	CFTG
	ADDERALL 15						
AB	SHIRE LABS	3.75MG;3.75MG;3.75MG;3.75MG		N11522 013	AUG 31, 2000	MAR	CFTG
	ADDERALL 7.5						
AB	SHIRE LABS	1.875MG;1.875MG;1.875MG;1.875MG		N11522 011	AUG 31, 2000	MAR	CFTG
	DEXTROAMP SACCHARATE, AMP ASPARTATE, DEXTROAMP SULFATE AND AMP SULFATE						
AB	BARR	1.875MG;1.875MG;1.875MG;1.875MG		N40422 005	MAR 19, 2003	MAR	NEWA
AB		3.125MG;3.125MG;3.125MG;3.125MG		N40422 006	MAR 19, 2003	MAR	NEWA
AB		3.75MG;3.75MG;3.75MG;3.75MG		N40422 007	MAR 19, 2003	MAR	NEWA

AMPRENAVIR

CAPSULE; ORAL

AGENERASE

GLAXOSMITHKLINE

		50MG		N21007 001	APR 15, 1999	MAR	CMFD
+		150MG		N21007 002	APR 15, 1999	MAR	CMFD

AMPRENAVIR

SOLUTION; ORAL

AGENERASE

+ GLAXOSMITHKLINE	15MG/ML	N21039 001	APR 15, 1999	MAR	CMFD
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APREPITANT

CAPSULE; ORAL

EMEND

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

ASPIRIN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL

FIORINAL

AB + WATSON PHARMS	325MG;50MG;40MG	N17534 005	APR 16, 1986	MAR	CAHN
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TABLET; ORAL

AB + WATSON PHARMS	325MG;50MG;40MG	N17534 003	APR 16, 1986	MAR	CAHN
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ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE

CAPSULE; ORAL

FIORINAL W/CODEINE NO 3

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

AZELASTINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

OPTIVAR

>A>	+ MEDPOINTE	0.05%	N21127 001	MAY 22, 2000	APR	CAHN
>D>	+ MURO	0.05%	N21127 001	MAY 22, 2000	APR	CAHN

BECLOMETHASONE DIPROPIONATE

AEROSOL, METERED; INHALATION

BECLOVENT

@ GLAXOSMITHKLINE	0.042MG/INH	N18153 001		MAR	DISC
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AEROSOL, METERED; NASAL

BECONASE

@ GLAXOSMITHKLINE	0.042MG/INH	N18584 001		MAR	DISC
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VANCENASE

@ SCHERING	0.042MG/INH	N18521 001		MAR	DISC
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BETAMETHASONE

TABLET; ORAL

CELESTONE

@ SCHERING

0.6MG

N12657 003

FEB DISC

BISOPROLOL FUMARATE

TABLET; ORAL

ZEBETA

AB WYETH PHARMS INC

5MG

N19982 002 JUL 31, 1992 MAR CAHN

AB +

10MG

N19982 001 JUL 31, 1992 MAR CAHN

BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

ZIAC

AB WYETH PHARMS INC

2.5MG;6.25MG

N20186 003 MAR 26, 1993 MAR CAHN

AB

5MG;6.25MG

N20186 001 MAR 26, 1993 MAR CAHN

AB +

10MG;6.25MG

N20186 002 MAR 26, 1993 MAR CAHN

BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

SYRUP; ORAL

DIMETANE-DX

@ ROBINS AH

2MG/5ML;10MG/5ML;30MG/5ML

N19279 001 AUG 24, 1984 MAR DISC

MYPHETANE DX

AA + MORTON GROVE

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

AP GENZIA SICOR PHARMS

0.001MG/ML

N75823 001 MAR 31, 2003 MAR NEWA

AP

0.002MG/ML

N75823 002 MAR 31, 2003 MAR NEWA

CARBINOXAMINE MALEATE

&gt;A&gt; SOLUTION; ORAL

&gt;A&gt; CARBINOXAMINE MALEATE

&gt;A&gt; + MIKART

4MG/5ML

N40458 001 APR 25, 2003 APR NEWA

TABLET; ORAL

+ MIKART

4MG

N40442 001 MAR 19, 2003 MAR NEWA

CARVEDILOL

TABLET; ORAL

COREG

&gt;D&gt; GLAXOSMITHKLINE

12.5MG

N20297 002 SEP 14, 1995 APR CRLD

&gt;A&gt;

+

12.5MG

N20297 002 SEP 14, 1995 APR CRLD

&gt;D&gt;

+

25MG

N20297 001 SEP 14, 1995 APR CRLD

&gt;A&gt;

25MG

N20297 001 SEP 14, 1995 APR CRLD

CEFADROXIL/CEFADROXIL HEMIHYDRATE

FOR SUSPENSION; ORAL

## CEFADROXIL

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

>D> CEFIXIME

&gt;D&gt; FOR SUSPENSION; ORAL

&gt;D&gt; SUPRAX

>D>	+	LEDERLE	100MG/5ML	N50622 001	APR 28, 1989	APR	DISC
>A>		@	100MG/5ML	N50622 001	APR 28, 1989	APR	DISC
>D>	TABLET; ORAL						
>D>	+	LEDERLE	200MG	N50621 001	APR 28, 1989	APR	DISC
>A>		@	200MG	N50621 001	APR 28, 1989	APR	DISC
>D>	+		400MG	N50621 002	APR 28, 1989	APR	DISC
>A>		@	400MG	N50621 002	APR 28, 1989	APR	DISC

CEFOXITIN SODIUM

INJECTABLE; INJECTION

MEFOXIN IN PLASTIC CONTAINER

+	MERCK	EQ 20MG BASE/ML	N63182 001	JAN 25, 1993	MAR	CRLD
+		EQ 40MG BASE/ML	N63182 002	JAN 25, 1993	MAR	CRLD

CEFUROXIME AXETIL

TABLET; ORAL

CEFUROXIME AXETIL

>A>	AB	RANBAXY	EQ 125MG BASE	N65118 001	APR 25, 2003	APR	NEWA
>A>	AB		EQ 250MG BASE	N65118 002	APR 25, 2003	APR	NEWA
>A>	AB		EQ 500MG BASE	N65118 003	APR 25, 2003	APR	NEWA

CEPHALOTHIN SODIUM

INJECTABLE; INJECTION

CEPHALOTHIN SODIUM

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

CICLOPIROX

SHAMPOO; TOPICAL

LOPROX

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

INJECTABLE; INJECTION

LEUSTATIN

>D>	+	ORTHO BIOTECH	1MG/ML	N20229 001	FEB 26, 1993	APR	CTEC
>A>	AP +		1MG/ML	N20229 001	FEB 26, 1993	APR	CTEC

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL

CLINDAMYCIN HCL

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

TABLET, ORALLY DISINTEGRATING; ORAL

KLONOPIN RAPIDLY DISINTEGRATING

>D>		@ ROCHE	0.125MG	N20813 001	DEC 23, 1997	APR	CMFD
>A>			0.125MG	N20813 001	DEC 23, 1997	APR	CMFD
>D>		@	0.25MG	N20813 002	DEC 23, 1997	APR	CMFD
>A>			0.25MG	N20813 002	DEC 23, 1997	APR	CMFD
>D>		@	0.5MG	N20813 003	DEC 23, 1997	APR	CMFD
>A>			0.5MG	N20813 003	DEC 23, 1997	APR	CMFD
>D>		@	1MG	N20813 004	DEC 23, 1997	APR	CMFD
>A>	+		1MG	N20813 004	DEC 23, 1997	APR	CMFD
>D>		@	2MG	N20813 005	DEC 23, 1997	APR	CMFD
>A>			2MG	N20813 005	DEC 23, 1997	APR	CMFD

COPPER

INTRAUTERINE DEVICE; INTRAUTERINE

COPPER T MODEL TCU 380A

+	FEI		309MG/COPPER	N18680 001	NOV 15, 1984	MAR	CAHN
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CORTISONE ACETATE

TABLET; ORAL

CORTISONE ACETATE

>D>	BP	PHARMACIA AND UPJOHN	25MG	N08126 001		APR	CRLD
>A>	BP +		25MG	N08126 001		APR	CRLD
>D>		CORTONE					
>D>	BP +	MERCK	25MG	N07750 003		APR	DISC
>A>		@	25MG	N07750 003		APR	DISC

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL

FLEXERIL

>D>	AA	MCNEIL CONS SPECLT	5MG	N17821 001		APR	CTEC
>A>			5MG	N17821 001		APR	CTEC
	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

CYCLOSPORINE

EMULSION; OPHTHALMIC  
RESTASIS

+ ALLERGAN 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

@ WYETH PHARMS INC 75MG N50261 001 MAR CAHN  
150MG N50261 002 MAR CAHN  
+ 300MG N50261 003 MAR CAHN

>A> DESIRUDIN

>A> INJECTABLE; SUBCUTANEOUS  
>A> IPRIVASK

>A> + AVENTIS PHARMS 15MG/VIAL N21271 001 APR 04, 2003 APR NEWA

DESOGESTREL; ETHINYL ESTRADIOL

TABLET; ORAL-21  
ORTHO-CEPT

@ ORTHO MCNEIL PHARM 0.15MG;0.03MG N20301 001 DEC 14, 1992 MAR DISC

TABLET; ORAL-28

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

DEXAMETHASONE

ELIXIR; ORAL

>D> DECADRON

>D> AA + MERCK 0.5MG/5ML N12376 002 APR DISC

>A> @ 0.5MG/5ML N12376 002 APR DISC

HEXADROL

>D> AA ORGANON 0.5MG/5ML N12674 001 APR CRLD

>A> AA + 0.5MG/5ML N12674 001 APR CRLD

DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

DEXAMETHASONE SODIUM PHOSPHATE

>A> AP AM PHARM EQ 10MG PHOSPHATE/ML N40491 001 APR 11, 2003 APR NEWA

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



DOXYCYCLINE HYCLATE

INJECTABLE; INJECTION

VIBRAMYCIN

@ PFIZER

EQ 100MG BASE/VIAL

N50442 002

MAR DISC

@

EQ 200MG BASE/VIAL

N50442 001

MAR DISC

ELETRIPTAN HYDROBROMIDE

TABLET; ORAL

RELPAX

PFIZER IRELAND

EQ 20MG BASE

N21016 001 DEC 26, 2002 MAR CAHN

+

EQ 40MG BASE

N21016 002 DEC 26, 2002 MAR CAHN

ENALAPRIL MALEATE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

ENALAPRIL MALEATE AND HYDROCHLOROTHIAZIDE

AB IVAX PHARMS

5MG;12.5MG

N75736 001 MAR 25, 2003 MAR NEWA

AB

10MG;25MG

N75736 002 MAR 25, 2003 MAR NEWA

ENFUVRTIDE

INJECTABLE; SUBCUTANEOUS

FUZEON

+ 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

@ DENTSPLY PHARM

0.005MG/ML;1.5%

N21384 001

MAR DISC

ERGOTAMINE TARTRATE

TABLET; SUBLINGUAL

ERGOMAR

+ HARVEST PHARMS

2MG

N87693 001 FEB 24, 1983 MAR CAHN

ERYTHROMYCIN

SOLUTION; TOPICAL

STATICIN

&gt;D&gt; AT + WESTWOOD SQUIBB

1.5%

N50526 001

APR CTEC

&gt;A&gt;

+

1.5%

N50526 001

APR CTEC

ESMOLOL HYDROCHLORIDE

INJECTABLE; INJECTION

BREVIBLOC DOUBLE STRENGTH IN PLASTIC CONTAINER

+ BAXTER HLHCARE CORP 2GM/100ML

N19386 005 JAN 27, 2003 MAR NEWA

BREVIBLOC IN PLASTIC CONTAINER

+ BAXTER HLHCARE CORP 1GM/100ML

N19386 004 FEB 16, 2001 MAR NEWA

ESTRADIOL ACETATEINSERT, EXTENDED RELEASE; VAGINAL  
FEMRING

GALEN LTD	0.05MG/24HR	N21367 001	MAR 20, 2003	MAR	NEWA
+	0.1MG/24HR	N21367 002	MAR 20, 2003	MAR	NEWA

ESTROGENS, CONJUGATEDCREAM; TOPICAL, VAGINAL  
PREMARIN

+ WYETH PHARMS INC	0.625MG/GM	N20216 001		MAR	CAHN
INJECTABLE; INJECTION					
+ WYETH PHARMS INC	25MG/VIAL	N10402 001		MAR	CAHN
TABLET; ORAL					
WYETH PHARMS INC	0.3MG	N04782 003		MAR	CAHN
+	0.625MG	N04782 004		MAR	CAHN
	0.9MG	N04782 005	JAN 26, 1984	MAR	CAHN
+	1.25MG	N04782 001		MAR	CAHN
	2.5MG	N04782 002		MAR	CAHN

ESTROGENS, CONJUGATED; MEDROXYPROGESTERONE ACETATE

TABLET; ORAL-28

PREMPHASE (PREMARIN;CYCRIN 14/14)

@ WYETH PHARMS INC	0.625MG,0.625MG;5MG	N20303 002	DEC 30, 1994	MAR	CAHN
PREMPHASE 14/14					
+ WYETH PHARMS INC	0.625MG,0.625MG;5MG	N20527 002	NOV 17, 1995	MAR	CAHN
PREMPRO					
+ WYETH PHARMS INC	0.45MG;1.5MG	N20527 004	MAR 12, 2003	MAR	NEWA
+	0.625MG,0.625MG;2.5MG,2.5MG	N20527 001	NOV 17, 1995	MAR	CAHN
+	0.625MG,0.625MG;5MG,5MG	N20527 003	JAN 09, 1998	MAR	CAHN
PREMPRO (PREMARIN;CYCRIN)					
@ 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
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ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-21

ALESSE

AB1 +	WYETH PHARMS INC	0.02MG;0.1MG	N20683 001	MAR 27, 1997	MAR	CAHN	
LEVONORGESTREL AND ETHINYL ESTRADIOL							
>A>	AB1	BARR	0.02MG;0.1MG	N75862 001	APR 29, 2003	APR	NEWA
NORDETTE-21							
AB	+ WYETH PHARMS INC	0.03MG;0.15MG	N18668 001	MAY 10, 1982	MAR	CAHN	
TRIPHASIL-21							
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							
AB1	WYETH PHARMS INC	0.02MG;0.1MG	N20683 002	MAR 27, 1997	MAR	CAHN	

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-28

LEVONORGESTREL AND ETHINYL ESTRADIOL						
>A>	AB1 BARR	0.02MG;0.1MG	N75862 002	APR 29, 2003	APR	NEWA
	NORDETTE-28					
	AB WYETH PHARMS INC	0.03MG;0.15MG	N18782 001	JUL 21, 1982	MAR	CAHN
	TRIPHASIL-28					
	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

@ WATSON LABS

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

+ WATSON LABS

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; NORETHINDRONE ACETATE

TABLET; ORAL-21

ESTROSTEP 21

&gt;A&gt; @ GALEN CHEM

0.02MG,0.03MG,0.035MG;1MG,1MG,1MG

N20130 001 OCT 09, 1996 APR CAHN

&gt;D&gt; @ PARKE DAVIS

0.02MG,0.03MG,0.035MG;1MG,1MG,1MG

N20130 001 OCT 09, 1996 APR CAHN

LOESTRIN 21 1.5/30

&gt;A&gt; + GALEN CHEM

0.03MG;1.5MG

N17875 001

APR CAHN

&gt;D&gt; + PARKE DAVIS

0.03MG;1.5MG

N17875 001

APR CAHN

LOESTRIN 21 1/20

&gt;A&gt; + GALEN CHEM

0.02MG;1MG

N17876 001

APR CAHN

&gt;D&gt; + PARKE DAVIS

0.02MG;1MG

N17876 001

APR CAHN

TABLET; ORAL-28

ESTROSTEP FE

&gt;A&gt; + GALEN CHEM

0.02MG,0.03MG,0.035MG;1MG,1MG,1MG

N20130 002 OCT 09, 1996 APR CAHN

&gt;D&gt; + PARKE DAVIS

0.02MG,0.03MG,0.035MG;1MG,1MG,1MG

N20130 002 OCT 09, 1996 APR CAHN

LOESTRIN FE 1.5/30

&gt;A&gt; AB + GALEN CHEM

0.03MG;1.5MG

N17355 001

APR CAHN

&gt;D&gt; AB + PARKE DAVIS

0.03MG;1.5MG

N17355 001

APR CAHN

LOESTRIN FE 1/20

&gt;A&gt; AB + GALEN CHEM

0.02MG;1MG

N17354 001

APR CAHN

&gt;D&gt; AB + PARKE DAVIS

0.02MG;1MG

N17354 001

APR CAHN

ETHINYL ESTRADIOL; NORGESTREL

TABLET; ORAL-21		LO/OVRAL				
AB +	WYETH PHARMS INC OGESTREL 0.5/50-21	0.03MG;0.3MG	N17612 001		MAR	CAHN
AB	WATSON LABS OVRAL	0.05MG;0.5MG	N75406 001	DEC 15, 1999	FEB	CAHN
AB +	WYETH PHARMS INC TABLET; ORAL-28	0.05MG;0.5MG	N16672 001		MAR	CAHN
TABLET; ORAL-28		LO/OVRAL-28				
AB	WYETH PHARMS INC OGESTREL 0.5/50-28	0.03MG;0.3MG	N17802 001		MAR	CAHN
AB	WATSON LABS OVRAL-28	0.05MG;0.5MG	N75406 002	DEC 15, 1999	FEB	CAHN
AB	WYETH PHARMS INC	0.05MG;0.5MG	N16806 001		MAR	CAHN

ETHIONAMIDE

TABLET; ORAL		TRECATOR-SC				
+	WYETH PHARMS INC	250MG	N13026 002		MAR	CAHN

ETHOTOIN

TABLET; ORAL		PEGANONE				
+	OVATION PHARMS	250MG	N10841 001		MAR	CAHN
	@	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				
AB	WYETH PHARMS INC	200MG	N18922 002	JAN 31, 1991	MAR	CAHN
AB +		300MG	N18922 003	JAN 31, 1991	MAR	CAHN
TABLET; ORAL		LODINE XL				
AB	WYETH PHARMS INC	400MG	N18922 004	JUL 29, 1993	MAR	CAHN
AB +		500MG	N18922 005	JUN 28, 1996	MAR	CAHN
TABLET, EXTENDED RELEASE; ORAL		ETODOLAC				
AB	TARO	400MG	N76174 001	MAR 13, 2003	MAR	NEWA
AB		500MG	N76174 002	MAR 13, 2003	MAR	NEWA
AB		600MG	N76174 003	MAR 13, 2003	MAR	NEWA
TABLET, EXTENDED RELEASE; ORAL		ETODOLAC				
AB +	WYETH PHARMS INC	400MG	N20584 001	OCT 25, 1996	MAR	CAHN
AB +		500MG	N20584 003	JAN 20, 1998	MAR	CAHN
AB +		600MG	N20584 002	OCT 25, 1996	MAR	CAHN

FELBAMATE

SUSPENSION; ORAL

FELBATOL

+	MEDPOINTE	600MG/5ML	N20189 003	JUL 29, 1993	MAR	CAHN
	TABLET; ORAL					
	MEDPOINTE	400MG	N20189 001	JUL 29, 1993	MAR	CAHN
+		600MG	N20189 002	JUL 29, 1993	MAR	CAHN

FENOFIBRATE

CAPSULE; ORAL

FENOFIBRATE (MICRONIZED)

	TEVA	67MG	N75753 001	SEP 03, 2002	MAR	CTEC
		134MG	N75753 002	APR 09, 2002	MAR	CTEC
+		200MG	N75753 003	APR 09, 2002	MAR	CRLD
	TRICOR (MICRONIZED)					
	@ ABBOTT	67MG	N19304 002	FEB 09, 1998	MAR	DISC
	@	134MG	N19304 003	JUN 30, 1999	MAR	DISC
	@	200MG	N19304 004	JUN 30, 1999	MAR	DISC

FLAVOXATE HYDROCHLORIDE

TABLET; ORAL

URISPAS

+	ORTHO-MCNEIL PHARMAC	100MG	N16769 001		MAR	CAHN
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FLECAINIDE ACETATE

TABLET; ORAL

FLECAINIDE ACETATE

AB	RANBAXY	50MG	N76421 001	MAR 28, 2003	MAR	NEWA
AB		100MG	N76421 002	MAR 28, 2003	MAR	NEWA
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
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FLUORESCEIN SODIUM

INJECTABLE; INJECTION

FUNDUSCEIN-25

@	NOVARTIS	25%	N17869 001		JAN	DISC
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FLUVOXAMINE MALEATE

TABLET; ORAL

FLUVOXAMINE MALEATE

>A>	AB	GENEVA PHARMS	25MG	N75887 001	JAN 05, 2001	APR	CAHN
>A>	AB		50MG	N75887 002	JAN 05, 2001	APR	CAHN
>A>	AB		100MG	N75887 003	JAN 05, 2001	APR	CAHN
>D>	AB	INVAMED	25MG	N75887 001	JAN 05, 2001	APR	CAHN
>D>	AB		50MG	N75887 002	JAN 05, 2001	APR	CAHN

>D>	AB	100MG		N75887 003	JAN 05, 2001	APR	CAHN
	<u>FOLIC ACID</u>						
	INJECTABLE; INJECTION						
	FOLVITE						
AP	+	WYETH PHARMS INC	5MG/ML	N05897 008		MAR	CAHN
	TABLET; ORAL						
		@ WYETH PHARMS INC	1MG	N05897 004		MAR	CAHN
	<u>GALANTAMINE HYDROBROMIDE</u>						
	TABLET; ORAL						
	REMINYL						
>D>		JANSSEN PHARMA	EQ 4MG BASE	N21169 001	FEB 28, 2001	APR	CRLD
>A>	+		EQ 4MG BASE	N21169 001	FEB 28, 2001	APR	CRLD
>D>	+		EQ 12MG BASE	N21169 003	FEB 28, 2001	APR	CRLD
>A>			EQ 12MG BASE	N21169 003	FEB 28, 2001	APR	CRLD
	<u>GATIFLOXACIN</u>						
	INJECTABLE; INJECTION						
	TEQUIN						
>D>		BRISTOL MYERS SQUIBB	EQ 2MG /ML(200MG/100ML)	N21062 001	DEC 17, 1999	APR	CRLD
>D>			EQ 2MG /ML(400MG/200ML)	N21062 002	DEC 17, 1999	APR	CRLD
>A>	+		EQ 2MG /ML(200MG/100ML)	N21062 001	DEC 17, 1999	APR	CRLD
>A>	+		EQ 2MG /ML(400MG/200ML)	N21062 002	DEC 17, 1999	APR	CRLD
>D>			EQ 10MG /ML(200MG)	N21062 003	DEC 17, 1999	APR	CRLD
>A>	+		EQ 10MG /ML(200MG)	N21062 003	DEC 17, 1999	APR	CRLD
	SOLUTION/DROPS; OPHTHALMIC						
	ZYMAR						
	+	ALLERGAN	0.3%	N21493 001	MAR 28, 2003	MAR	NEWA
>A>	<u>GEMIFLOXACIN MESYLATE</u>						
>A>	TABLET; ORAL						
>A>	FACTIVE						
>A>	+	LG LIFE	EQ 320MG BASE	N21158 001	APR 04, 2003	APR	NEWA
	<u>GEMTUZUMAB OZOGAMICIN</u>						
	INJECTABLE; INJECTION						
	MYLOTARG						
	+	WYETH PHARMS INC	5MG/VIAL	N21174 001	MAY 17, 2000	MAR	CAHN
	<u>GENTAMICIN SULFATE</u>						
	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
	OINTMENT; OPHTHALMIC						
	GARAMYCIN						
>D>	AT	+	SCHERING	EQ 0.3% BASE	N50425 001		APR DISC
>A>		@		EQ 0.3% BASE	N50425 001		APR DISC
	GENTAMICIN SULFATE						
>D>	AT	AKORN	EQ 0.3% BASE	N64093 001	AUG 31, 1995	APR	CRLD
>A>	+		EQ 0.3% BASE	N64093 001	AUG 31, 1995	APR	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

AB	WYETH PHARMS INC	25MG;40MG	N18031 001		MAR	CAHN
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INDERIDE-80/25

AB +	WYETH PHARMS INC	25MG;80MG	N18031 002		MAR	CAHN
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HYDROCODONE BITARTRATE; IBUPROFEN

TABLET; ORAL

&gt;A&gt; HYDROCODONE BITARTRATE AND IBUPROFEN

>A>	AB	TEVA	7.5MG;200MG	N76023 001	APR 11, 2003	APR	NEWA
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VICOPROFEN

>D>	+	ABBOTT	7.5MG;200MG	N20716 001	SEP 23, 1997	APR	CFTG
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>A>	AB +		7.5MG;200MG	N20716 001	SEP 23, 1997	APR	CFTG
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>D> HYDROCORTISONE SODIUM PHOSPHATE

&gt;D&gt; INJECTABLE; INJECTION

&gt;D&gt; HYDROCORTONE

>D>	+	MERCK	EQ 50MG BASE/ML	N12052 001		APR	DISC
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>A>	@		EQ 50MG BASE/ML	N12052 001		APR	DISC
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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
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SUSPENSION/DROPS; OPHTHALMIC

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

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

INJECTABLE; INJECTION

HYDROMORPHONE HCL

>A>	AP	FAULDING	10MG/ML	N76444 001	APR 25, 2003	APR	NEWA
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HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL

ATARAX

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

AB +	SIDMAK LABS NJ	10MG	N88617 001	JAN 10, 1986	FEB	CRLD
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AB +		25MG	N88618 001	JAN 10, 1986	FEB	CRLD
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AB +		50MG	N88619 001	JAN 10, 1986	FEB	CRLD
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	@	100MG		N81054 001	SEP 25, 1995	FEB	DISC
<u>IMATINIB MESYLATE</u>							
>A>		TABLET; ORAL					
>A>		GLEEVEC					
>A>		NOVARTIS	100MG	N21588 001	APR 18, 2003	APR	NEWA
>A>	+		400MG	N21588 002	APR 18, 2003	APR	NEWA
<u>IPRATROPIUM BROMIDE</u>							
SPRAY, METERED; NASAL							
ATROVENT							
AB	+	BOEHRINGER INGELHEIM	0.021MG/SPRAY	N20393 001	OCT 20, 1995	MAR	CFTG
AB	+		0.042MG/SPRAY	N20394 001	OCT 20, 1995	MAR	CFTG
IPRATROPIUM BROMIDE							
AB		BAUSCH AND LOMB	0.021MG/SPRAY	N76025 001	MAR 31, 2003	MAR	NEWA
AB			0.042MG/SPRAY	N76103 001	MAR 31, 2003	MAR	NEWA
AB		DEY	0.021MG/SPRAY	N75552 001	MAR 31, 2003	MAR	NEWA
AB			0.042MG/SPRAY	N75553 001	MAR 31, 2003	MAR	NEWA
>A>	AB	NOVEX	0.021MG/SPRAY	N76156 001	APR 18, 2003	APR	NEWA
>A>	AB		0.042MG/SPRAY	N76155 001	APR 18, 2003	APR	NEWA
<u>ISOSORBIDE DINITRATE</u>							
TABLET; ORAL							
ISORDIL							
AB		WYETH PHARMS INC	5MG	N12093 007	JUL 29, 1988	MAR	CAHN
AB			10MG	N12093 002	JUL 29, 1988	MAR	CAHN
AB			20MG	N12093 006	JUL 29, 1988	MAR	CAHN
AB	+		30MG	N12093 005	JUL 29, 1988	MAR	CAHN
AB			40MG	N12093 001	JUL 29, 1988	MAR	CAHN
TABLET; SUBLINGUAL							
AB		WYETH PHARMS INC	2.5MG	N12940 004	JUL 29, 1988	MAR	CAHN
AB			5MG	N12940 003	JUL 29, 1988	MAR	CAHN
	+		10MG	N12940 005	JUL 29, 1988	MAR	CAHN
<u>ISOTRETINOIN</u>							
CAPSULE; ORAL							
CLARAVIS							
>A>	AB	BARR	10MG	N76356 001	APR 11, 2003	APR	NEWA
>A>	AB		20MG	N76135 002	APR 11, 2003	APR	NEWA
>A>	AB		40MG	N76135 001	APR 11, 2003	APR	NEWA
<u>KETOPROFEN</u>							
CAPSULE, EXTENDED RELEASE; ORAL							
ORUVAIL							
AB		WYETH PHARMS INC	100MG	N19816 003	FEB 08, 1995	MAR	CAHN
AB			150MG	N19816 002	FEB 08, 1995	MAR	CAHN
AB	+		200MG	N19816 001	SEP 24, 1993	MAR	CAHN
<u>LACTULOSE</u>							
SOLUTION; ORAL							
LACTULOSE							
AA		VISTAPHARM	10GM/15ML	N74138 001	SEP 30, 1992	MAR	CAHN

LEFLUNOMIDE

TABLET; ORAL

ARAVA

+	AVENTIS PHARMS	20MG	N20905 002	SEP 10, 1998	MAR	CRLD
	@	100MG	N20905 003	SEP 10, 1998	MAR	DISC

LEUPROLIDE ACETATE

INJECTABLE; SUBCUTANEOUS

ELIGARD

+	ATRIX	30MG/VIAL	N21488 001	FEB 13, 2003	FEB	NEWA
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LEVOBETAXOLOL HYDROCHLORIDE

SUSPENSION/DROPS; OPHTHALMIC

BETAXON

+	MEDPOINTE	EQ 0.5% BASE	N21114 001	FEB 23, 2000	MAR	CAHN
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LEVONORGESTREL

IMPLANT; IMPLANTATION

LEVONORGESTREL

BX	+	WYETH PHARMS INC	75MG/IMPLANT	N20627 001	AUG 15, 1996	MAR	CAHN
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NORPLANT SYSTEM IN PLASTIC CONTAINER

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

TABLET; ORAL

LEVO-DROMORAN

@ ICN

2MG

N08720 001	DEC 19, 1991	FEB	DISC
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LEVORPHANOL TARTRATE

+	ROXANE	2MG	N74278 001	MAR 31, 2000	FEB	CRLD
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LEVOTHYROXINE SODIUM

TABLET; ORAL

LEVO-T

>A>	BX	ALARA PHARM	0.025MG	N21342 001	MAR 01, 2002	APR	CAHN
>A>	BX		0.05MG	N21342 002	MAR 01, 2002	APR	CAHN
>A>	BX		0.075MG	N21342 003	MAR 01, 2002	APR	CAHN
>A>	BX		0.088MG	N21342 004	MAR 01, 2002	APR	CAHN
>A>	BX		0.1MG	N21342 005	MAR 01, 2002	APR	CAHN
>A>	BX		0.112MG	N21342 006	MAR 01, 2002	APR	CAHN
>A>	BX		0.125MG	N21342 007	MAR 01, 2002	APR	CAHN
>A>	BX		0.15MG	N21342 008	MAR 01, 2002	APR	CAHN
>A>	BX		0.175MG	N21342 009	MAR 01, 2002	APR	CAHN
>A>	BX		0.2MG	N21342 010	MAR 01, 2002	APR	CAHN
>A>	BX	+	0.3MG	N21342 011	MAR 01, 2002	APR	CAHN
>D>	BX	MOVA	0.025MG	N21342 001	MAR 01, 2002	APR	CAHN
>D>	BX		0.05MG	N21342 002	MAR 01, 2002	APR	CAHN
>D>	BX		0.075MG	N21342 003	MAR 01, 2002	APR	CAHN
>D>	BX		0.088MG	N21342 004	MAR 01, 2002	APR	CAHN
>D>	BX		0.1MG	N21342 005	MAR 01, 2002	APR	CAHN
>D>	BX		0.112MG	N21342 006	MAR 01, 2002	APR	CAHN
>D>	BX		0.125MG	N21342 007	MAR 01, 2002	APR	CAHN
>D>	BX		0.15MG	N21342 008	MAR 01, 2002	APR	CAHN

>D>	BX	0.175MG	N21342 009	MAR 01, 2002	APR	CAHN
>D>	BX	0.2MG	N21342 010	MAR 01, 2002	APR	CAHN
>D>	BX +	0.3MG	N21342 011	MAR 01, 2002	APR	CAHN

LIDOCAINE HYDROCHLORIDE

JELLY; TOPICAL

LIDOCAINE HCL

AT	AKORN	2%	N40433 001	FEB 12, 2003	FEB	NEWA
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LISINOPRIL

TABLET; ORAL

LISINOPRIL

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

>D>	AB +	ASTRAZENECA	30MG	N19777 006	JAN 20, 1999	APR	CRLD
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>A>	AB		30MG	N19777 006	JAN 20, 1999	APR	CRLD
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LITHIUM CARBONATE

CAPSULE; ORAL

LITHIUM CARBONATE

AB	ROXANE	150MG	N17812 002	JAN 28, 1987	FEB	CTEC
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AB	WEST WARD	150MG	N76243 002	FEB 24, 2003	FEB	NEWA
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TABLET, EXTENDED RELEASE; ORAL

>A>	AB	ABLE	300MG	N76382 001	APR 21, 2003	APR	NEWA
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LORAZEPAM

INJECTABLE; INJECTION

ATIVAN

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

TABLET; ORAL

INVERSINE

>D>	+	LAYTON	2.5MG	N10251 001		APR	CAHN
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>A>	+	TARGACEPT	2.5MG	N10251 001		APR	CAHN
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MEFLOQUINE HYDROCHLORIDE

TABLET; ORAL

MEFLOQUINE HCL

>A>	AB	GENEVA PHARMS	250MG	N76175 001	FEB 20, 2002	APR	CAHN
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>D>	AB	GENEVA PHARMS TECH	250MG	N76175 001	FEB 20, 2002	APR	CAHN
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MEPHENTERMINE SULFATE

INJECTABLE; INJECTION

WYAMINE SULFATE

@ BAXTER HLTHCARE CORP EQ 15MG BASE/ML

N08248 002	FEB	CAHN
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@ EQ 30MG BASE/ML

N08248 001	FEB	CAHN
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MEPROBAMATE

TABLET; ORAL

MILTOWN

>A>	AA +	MEDPOINTE	600MG	N83919 001		APR	CAHN
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>D>	AA +	WALLACE PHARMS	600MG	N83919 001		APR	CAHN
<u>METFORMIN HYDROCHLORIDE</u>							
TABLET; ORAL							
METFORMIN HCL							
AB		PUREPAC PHARM	1GM	N76033 003	JAN 24, 2002	FEB	CMS1
TABLET, EXTENDED RELEASE; ORAL							
GLUCOPHAGE XR							
>A>	+	BRISTOL MYERS SQUIBB	750MG	N21202 004	APR 11, 2003	APR	NEWA
<u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE</u>							
TABLET; ORAL							
AVANDAMET							
>D>		GLAXOSMITHKLINE	500MG;EQ 1MG BASE	N21410 001	OCT 10, 2002	APR	CAHN
>D>			500MG;EQ 2MG BASE	N21410 002	OCT 10, 2002	APR	CAHN
>D>	+		500MG;EQ 4MG BASE	N21410 003	OCT 10, 2002	APR	CAHN
>A>		SB PHARMCO	500MG;EQ 1MG BASE	N21410 001	OCT 10, 2002	APR	CAHN
>A>	+		500MG;EQ 4MG BASE	N21410 003	OCT 10, 2002	APR	CAHN
>A>			500MG;EQ 2MG BASE	N21410 002	OCT 10, 2002	APR	CAHN
<u>METHADONE HYDROCHLORIDE</u>							
INJECTABLE; INJECTION							
DOLOPHINE HCL							
>A>	+	AAIPHARMA	10MG/ML	N21624 001		APR	CAHN
>D>	+	ROXANE	10MG/ML	N21624 001		APR	CAHN
	+		10MG/ML	N21624 001		FEB	CMS1
<u>METHOCARBAMOL</u>							
TABLET; ORAL							
METHOCARBAMOL							
AA		ABLE	500MG	N40413 001	MAR 17, 2003	MAR	NEWA
AA			750MG	N40413 002	MAR 17, 2003	MAR	NEWA
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
<u>METHOTREXATE SODIUM</u>							
INJECTABLE; INJECTION							
METHOTREXATE LPF							
AP	+	WYETH PHARMS INC	EQ 25MG BASE/ML	N11719 007	MAR 31, 1982	MAR	CAHN
METHOTREXATE SODIUM							
		@ WYETH PHARMS INC	EQ 2.5MG BASE/ML	N11719 004		MAR	CAHN
	+		EQ 20MG BASE/VIAL	N11719 001		MAR	CAHN
AP	+		EQ 25MG BASE/ML	N11719 005		MAR	CAHN
		@	EQ 50MG BASE/VIAL	N11719 003		MAR	CAHN
		@	EQ 100MG BASE/VIAL	N11719 006		MAR	CAHN
METHOTREXATE SODIUM PRESERVATIVE FREE							
AP	+	WYETH PHARMS INC	EQ 1GM BASE/VIAL	N11719 009	APR 07, 1988	MAR	CAHN
<u>METHSCOPOLAMINE BROMIDE</u>							
TABLET; ORAL							
PAMINE FORTE							
	+	BRADLEY PHARMS	5MG	N08848 002	MAR 25, 2003	MAR	NEWA

METHYLPHENIDATE HYDROCHLORIDE

>A>		TABLET, CHEWABLE; ORAL						
>A>		METHYLIN						
>A>		MALLINCKRODT	2.5MG	N21475 001	APR 15, 2003	APR	NEWA	
>A>			5MG	N21475 002	APR 15, 2003	APR	NEWA	
>A>		+	10MG	N21475 003	APR 15, 2003	APR	NEWA	

METOCLOPRAMIDE HYDROCHLORIDE

		SOLUTION; ORAL						
		METOCLOPRAMIDE						
>D>	AA	UDL	EQ 5MG BASE/5ML	N75051 001	JAN 26, 2001	APR	CAHN	
>A>	AA	VISTAPHARM	EQ 5MG BASE/5ML	N75051 001	JAN 26, 2001	APR	CAHN	

MINOCYCLINE HYDROCHLORIDE

		CAPSULE; ORAL						
		MINOCIN						
AB		WYETH PHARMS INC	EQ 50MG BASE	N50649 001	MAY 31, 1990	MAR	CAHN	
AB			EQ 75MG BASE	N50649 003	FEB 12, 2001	MAR	CAHN	
AB		+	EQ 100MG BASE	N50649 002	MAY 31, 1990	MAR	CAHN	
		INJECTABLE; INJECTION						
		+	WYETH PHARMS INC	EQ 100MG BASE/VIAL	N50444 001		MAR	CAHN
>A>		TABLET; ORAL						
>A>		MINOCYCLINE HCL						
>A>		PAR PHARM	EQ 50MG BASE	N65131 001	APR 16, 2003	APR	NEWA	
>A>			EQ 75MG BASE	N65131 002	APR 16, 2003	APR	NEWA	
>A>		+	EQ 100MG BASE	N65131 003	APR 16, 2003	APR	NEWA	

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	

MOXIFLOXACIN HYDROCHLORIDE

>A>		SOLUTION/DROPS; OPHTHALMIC						
>A>		VIGAMOX						
>A>		+	ALCON	0.5%	N21598 001	APR 15, 2003	APR	NEWA

MUPIROCIN

		OINTMENT; TOPICAL						
		MUPIROCIN						
>D>	BX	CLAY PARK LABS	2%	N50788 001	DEC 04, 2002	APR	CAHN	
	BX		2%	N50788 001	DEC 04, 2002	JAN	CTEC	
>A>	BX	JOHNSON AND JOHNSON	2%	N50788 001	DEC 04, 2002	APR	CAHN	

MYCOPHENOLATE MOFETIL

		CAPSULE; ORAL						
		CELLCEPT						
		+	ROCHE PALO	250MG	N50722 001	MAY 03, 1995	FEB	CAHN

MYCOPHENOLATE MOFETIL

SUSPENSION; ORAL

CELLCEPT

+ 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

&gt;D&gt; + ELAN PHARM EQ 375MG BASE N20353 001 JAN 05, 1996 APR CFTG

&gt;A&gt; AB + EQ 375MG BASE N20353 001 JAN 05, 1996 APR CFTG

AB + EQ 500MG BASE N20353 002 JAN 05, 1996 MAR CFTG

&gt;A&gt; NAPROXEN SODIUM

&gt;A&gt; AB ANDRX PHARMS EQ 375MG BASE N75416 002 APR 23, 2003 APR NEWA

AB EQ 500MG BASE N75416 001 AUG 27, 2002 MAR NEWA

NELFINAVIR MESYLATE

TABLET; ORAL

VIRACEPT

&gt;A&gt; + AGOURON EQ 625MG BASE N21503 001 APR 30, 2003 APR NEWA

NITROFURANTOIN

&gt;D&gt; TABLET; ORAL

&gt;D&gt; FURADANTIN

&gt;D&gt; AB PROCTER AND GAMBLE 50MG N08693 001 APR DISC

&gt;A&gt; @ 50MG N08693 001 APR DISC

&gt;D&gt; AB + 100MG N08693 002 APR DISC

&gt;A&gt; @ 100MG N08693 002 APR DISC

&gt;D&gt; NITROFURANTOIN

&gt;D&gt; AB WATSON LAB 50MG N80447 001 APR DISC

&gt;A&gt; @ 50MG N80447 001 APR DISC

&gt;D&gt; AB WHITEWORTH TOWN PLSN 100MG N84085 002 APR DISC

&gt;A&gt; @ 100MG N84085 002 APR DISC

NITROFUZAZONE

OINTMENT; TOPICAL

FURACIN

@ SHIRE PHARM 0.2% N05795 001 MAR DISC

NITROGLYCERIN

FILM, EXTENDED RELEASE; TRANSDERMAL\*

## NITROGLYCERIN

>D>	AB2	MYLAN	0.1MG/HR	N75033 001	FEB 06, 1998	APR	CAHN
>D>	AB2		0.2MG/HR	N74609 001	AUG 30, 1996	APR	CAHN
>D>	AB2		0.4MG/HR	N74607 001	AUG 30, 1996	APR	CAHN
>D>	AB2		0.6MG/HR	N74559 001	AUG 30, 1996	APR	CAHN
>A>	AB2	MYLAN TECHNOLOGIES	0.1MG/HR	N75033 001	FEB 06, 1998	APR	CAHN
>A>	AB2		0.2MG/HR	N74609 001	AUG 30, 1996	APR	CAHN
>A>	AB2		0.4MG/HR	N74607 001	AUG 30, 1996	APR	CAHN
>A>	AB2		0.6MG/HR	N74559 001	AUG 30, 1996	APR	CAHN
OINTMENT; TRANSDERMAL							
>D>	+	ALTANA	2%	N87355 001	JUL 08, 1988	APR	CAHN
>A>	+	FOUGERA	2%	N87355 001	JUL 08, 1988	APR	CAHN

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

AP	+	ABBOTT	EQ 1MG BASE/ML	N07513 001		MAR	CFTG
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## NOREPINEPHRINE BITARTRATE

AP		GENSIA SICOR PHARMS	EQ 1MG BASE/ML	N40455 001	MAR 03, 2003	MAR	NEWA
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NORETHINDRONE ACETATE

TABLET; ORAL

## AYGESTIN

AB	+	WYETH PHARMS INC	5MG	N18405 001	APR 21, 1982	MAR	CAHN
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NORGESTREL

TABLET; ORAL

## OVRETTE

	+	WYETH PHARMS INC	0.075MG	N17031 001		MAR	CAHN
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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

AP		BEDFORD LABS	30MG/ML	N40463 001	MAR 04, 2003	MAR	NEWA
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\* SEE SECTION 1.3 NITROGLYCERIN, FILM, EXTENDED RELEASE; TRANSDERMAL

OXYBUTYNIN

FILM, EXTENDED RELEASE; TRANSDERMAL

OXYTROL

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

INJECTABLE; IV (INFUSION)

PROTONIX IV

	+ WYETH PHARMS INC	EQ 40MG BASE/VIAL	N20988 001	MAR 22, 2001	MAR	CAHN
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TABLET, DELAYED RELEASE; ORAL

PROTONIX

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

INJECTABLE; SUBCUTANEOUS

SOMAVERT

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

CREAM; TOPICAL

PERMETHRIN

>A>	AB	CLAY PARK	5%	N76369 001	APR 21, 2003	APR	NEWA
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PERPHENAZINE

TABLET; ORAL

PERPHENAZINE

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

	@	SCHERING	2MG	N10775 001		FEB	DISC
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	@		4MG	N10775 002		FEB	DISC
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	@		8MG	N10775 003		FEB	DISC
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	@		16MG	N10775 004		FEB	DISC
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PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

PHENTERMINE HCL

AA		ABLE	15MG	N40497 001	MAR 13, 2003	MAR	NEWA
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AA		AMIDE PHARM	15MG	N40460 001	JAN 14, 2003	JAN	NEWA
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AA			30MG	N40448 001	JAN 22, 2003	JAN	NEWA
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PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PHENERGAN VC

>D>								
>D>	AA	+	WYETH AYERST	5MG/5ML;6.25MG/5ML	N08604 003	APR 02, 1984	APR	DISC

>A>		@		5MG/5ML;6.25MG/5ML	N08604 003	APR 02, 1984	APR	DISC
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PROMETH VC PLAIN

>D>	AA		ALPHARMA	5MG/5ML;6.25MG/5ML	N88761 001	NOV 08, 1984	APR	CRLD
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>A>	AA +	5MG/5ML;6.25MG/5ML	N88761 001	NOV 08, 1984	APR	CRLD
	<u>PHENYTOIN</u>					
	SUSPENSION; ORAL					
	PHENYTOIN					
AB	VISTAPHARM	125MG/5ML	N40342 001	JAN 31, 2001	MAR	CAHN
	<u>PHENYTOIN SODIUM</u>					
	INJECTABLE; INJECTION					
	DILANTIN					
	@ PARKE DAVIS	50MG/ML	N10151 001		MAR	DISC
	PHENYTOIN					
+	ELKINS SINN	50MG/ML	N84307 001		MAR	CRLD
	PHENYTOIN SODIUM					
	@ ABBOTT	50MG/ML	N89521 001	MAR 17, 1987	MAR	DISC
	@	50MG/ML	N89744 001	DEC 18, 1987	MAR	DISC
	<u>PHENYTOIN SODIUM, EXTENDED</u>					
	CAPSULE; ORAL					
	DILANTIN					
	PARKE DAVIS	30MG	N84349 001		FEB	CRLD
	<u>PILOCARPINE HYDROCHLORIDE</u>					
	TABLET; ORAL					
	SALAGEN					
>D>	+	MGI PHARMA INC	5MG	N20237 001	MAR 22, 1994	APR CRLD
>A>			5MG	N20237 001	MAR 22, 1994	APR CRLD
>A>	+		7.5MG	N20237 002	APR 18, 2003	APR NEWA
	<u>PIPERACILLIN SODIUM</u>					
	INJECTABLE; INJECTION					
	PIPRACIL					
+	WYETH PHARMS INC	EQ 2GM BASE/VIAL	N50545 002		MAR	CAHN
		EQ 2GM BASE/VIAL	N62750 001	OCT 13, 1987	MAR	CAHN
+		EQ 3GM BASE/VIAL	N50545 003		MAR	CAHN
		EQ 3GM BASE/VIAL	N62750 002	OCT 13, 1987	MAR	CAHN
+		EQ 4GM BASE/VIAL	N50545 004		MAR	CAHN
		EQ 4GM BASE/VIAL	N62750 003	OCT 13, 1987	MAR	CAHN
	@	EQ 40GM BASE/VIAL	N50545 006	SEP 30, 1985	MAR	CAHN
	<u>PIPERACILLIN SODIUM; TAZOBACTAM SODIUM</u>					
	INJECTABLE; INJECTION					
	ZOSYN					
+	WYETH PHARMS INC	EQ 2GM BASE/VIAL;EQ 250MG BASE/VIAL	N50684 001	OCT 22, 1993	MAR	CAHN
+		EQ 3GM BASE/VIAL;EQ 375MG BASE/VIAL	N50684 002	OCT 22, 1993	MAR	CAHN
+		EQ 4GM BASE/VIAL;EQ 500MG BASE/VIAL	N50684 003	OCT 22, 1993	MAR	CAHN
+		EQ 36GM BASE/VIAL;EQ 4.5GM BASE/VIAL	N50684 004	OCT 22, 1993	MAR	CAHN
	ZOSYN IN PLASTIC CONTAINER					
+	WYETH PHARMS INC	EQ 40MG BASE/ML;EQ 5MG BASE/ML	N50750 001	FEB 24, 1998	MAR	CAHN
+		EQ 60MG BASE/ML;EQ 7.5MG BASE/ML	N50750 002	FEB 24, 1998	MAR	CAHN
+		EQ 4GM BASE/100ML;EQ 500MG BASE/100ML	N50750 003	FEB 24, 1998	MAR	CAHN

PRALIDOXIME CHLORIDE

INJECTABLE; INJECTION

PRALIDOXIME CHLORIDE

@ BAXTER HLTHCARE CORP 300MG/ML

N18799 001 DEC 13, 1982 MAR CAHN

PREDNICARBATE

CREAM; TOPICAL

&gt;A&gt; DERMATOP E EMOLLIENT

&gt;A&gt; + DERMIK LABS 0.1%

N20279 001 OCT 29, 1993 APR CTNA

&gt;D&gt; DERMATOP

&gt;D&gt; + DERMIK LABS 0.1%

N20279 001 OCT 29, 1993 APR CTNA

PREDNISOLONE

SYRUP; ORAL

PREDNISOLONE

AA HI TECH PHARMA 15MG/5ML

N40401 001 FEB 27, 2003 FEB NEWA

AA PHARM ASSOC 15MG/5ML

N40399 001 MAR 05, 2003 MAR NEWA

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION; ORAL

PREDNISOLONE SODIUM PHOSPHATE

AA HI TECH PHARMA EQ 5MG BASE/5ML

N75183 001 MAR 26, 2003 MAR NEWA

PREDNISOLONE SODIUM PHOSPHATE; SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC

SULFACETAMIDE SODIUM AND PREDNISOLONE SODIUM PHOSPHATE

&gt;A&gt; AT ALCON EQ 0.23% PHOSPHATE;10%

N73630 001 MAY 27, 1993 APR CAHN

&gt;D&gt; AT ALCON UNIVERSAL EQ 0.23% PHOSPHATE;10%

N73630 001 MAY 27, 1993 APR CAHN

PREDNISON

TABLET; ORAL

PREDNISON

AB VINTAGE PHARMS 20MG

N40392 001 FEB 12, 2003 FEB NEWA

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

&gt;D&gt; PHENERGAN

&gt;D&gt; AP + WYETH AYERST 50MG/ML

N08857 003 APR DISC

&gt;A&gt; @ 50MG/ML

N08857 003 APR DISC

PROMETHAZINE HCL

&gt;D&gt; AP GENSLA SICOR PHARMS 25MG/ML

N40454 001 AUG 22, 2002 APR CRLD

&gt;A&gt; AP + 25MG/ML

N40454 001 AUG 22, 2002 APR CRLD

&gt;D&gt; AP 50MG/ML

N40454 002 AUG 22, 2002 APR CRLD

&gt;A&gt; AP + 50MG/ML

N40454 002 AUG 22, 2002 APR CRLD

AP PHARMAFORCE 25MG/ML

N40515 001 MAR 19, 2003 MAR NEWA

SUPPOSITORY; RECTAL

PHENERGAN

AB + WYETH AYERST 50MG

N11689 001 FEB CTEC

AB WYETH PHARMS INC 12.5MG

N10926 002 MAR CAHN

AB + 25MG

N10926 001 MAR CAHN

AB + 50MG

N11689 001 MAR CAHN

PROMETHAZINE HCL

&gt;A&gt; AB ABLE 12.5MG

N40504 001 APR 11, 2003 APR NEWA

>A>	AB		25MG	N40504 002	APR 11, 2003	APR	NEWA
	AB		50MG	N40449 001	FEB 27, 2003	FEB	NEWA
	AB	G AND W LABS	12.5MG	N40428 002	MAR 31, 2003	MAR	NEWA
		TABLET; ORAL					
		PHENERGAN					
		WYETH PHARMS INC	12.5MG	N07935 002		MAR	CAHN
	BP		25MG	N07935 003		MAR	CAHN
	BP +		50MG	N07935 004		MAR	CAHN
	<u>PROPRANOLOL HYDROCHLORIDE</u>						
	CAPSULE, EXTENDED RELEASE; ORAL						
	INDERAL LA						
		WYETH PHARMS INC	60MG	N18553 004	MAR 18, 1987	MAR	CAHN
	BX		80MG	N18553 002	APR 19, 1983	MAR	CTEC
	BX		120MG	N18553 003	APR 19, 1983	MAR	CTEC
			160MG	N18553 001	APR 19, 1983	MAR	CAHN
		+ INNOPRAN XL					
	BX	RELIANT PHARMS	80MG	N21438 001	MAR 12, 2003	MAR	NEWA
	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						
	AB +	WYETH PHARMS INC	10MG	N16418 001		MAR	CAHN
	AB		20MG	N16418 003		MAR	CAHN
	AB		40MG	N16418 002		MAR	CAHN
	AB		60MG	N16418 009	OCT 18, 1982	MAR	CAHN
	AB +		80MG	N16418 004		MAR	CAHN
		@	90MG	N16418 010	OCT 18, 1982	MAR	CAHN
	<u>PYRIDOSTIGMINE BROMIDE</u>						
	TABLET; ORAL						
	PYRIDOSTIGMINE BROMIDE						
>A>	AB	IMPAX LABS	60MG	N40502 001	APR 24, 2003	APR	NEWA
		@ US ARMY	30MG	N20414 001	FEB 05, 2003	FEB	NEWA
	<u>QUETIAPINE FUMARATE</u>						
	TABLET; ORAL						
	SEROQUEL						
		ASTRAZENECA	EQ 25MG BASE	N20639 001	SEP 26, 1997	MAR	CRLD
	<u>QUINIDINE GLUCONATE</u>						
	TABLET, EXTENDED RELEASE; ORAL						
	QUINAGLUTE						
		@ BERLEX LABS	324MG	N16647 001		MAR	DISC
	QUINIDINE GLUCONATE						
>D>	BX	MUTUAL PHARM	324MG	N89338 001	FEB 11, 1987	APR	CRLD
>A>	BX +		324MG	N89338 001	FEB 11, 1987	APR	CRLD
>D>		+ WATSON LABS	324MG	N87810 001	SEP 29, 1982	APR	CRLD
>A>	BX		324MG	N87810 001	SEP 29, 1982	APR	CRLD
			324MG	N87810 001	SEP 29, 1982	MAR	CRLD

QUINIDINE SULFATE

TABLET, EXTENDED RELEASE; ORAL

QUINIDEX

AB +	WYETH PHARMS INC	300MG	N12796 002		MAR	CAHN
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RILUZOLE

TABLET; ORAL

RILUTEK

AB +	AVENTIS	50MG	N20599 001	DEC 12, 1995	JAN	CFTG
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RILUZOLE

AB	IMPAX LABS	50MG	N76173 001	JAN 29, 2003	JAN	NEWA
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RIMANTADINE HYDROCHLORIDE

TABLET; ORAL

RIMANTADINE HCL

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

&gt;A&gt; TABLET, ORALLY DISINTEGRATING; ORAL

&gt;A&gt; RISPERDAL

>A>	JOHNSON AND JOHNSON	0.5MG	N21444 001	APR 02, 2003	APR	NEWA
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>A>	+	1MG	N21444 002	APR 02, 2003	APR	NEWA
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>A>		2MG	N21444 003	APR 02, 2003	APR	NEWA
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ROSIGLITAZONE MALEATE

TABLET; ORAL

AVANDIA

>D>	GLAXOSMITHKLINE	EQ 2MG BASE	N21071 002	MAY 25, 1999	APR	CAHN
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>D>		EQ 4MG BASE	N21071 003	MAY 25, 1999	APR	CAHN
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>D>	+	EQ 8MG BASE	N21071 004	MAY 25, 1999	APR	CAHN
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>A>	SB PHARMCO	EQ 2MG BASE	N21071 002	MAY 25, 1999	APR	CAHN
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>A>		EQ 4MG BASE	N21071 003	MAY 25, 1999	APR	CAHN
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>A>	+	EQ 8MG BASE	N21071 004	MAY 25, 1999	APR	CAHN
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SEVELAMER HYDROCHLORIDE

CAPSULE; ORAL

RENAGEL

>D>	+	GELTEX	403MG	N20926 001	OCT 30, 1998	APR	CAHN
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>A>	+	GENZYME	403MG	N20926 001	OCT 30, 1998	APR	CAHN
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TABLET; ORAL

>D>		GELTEX	400MG	N21179 001	JUL 12, 2000	APR	CAHN
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>D>	+		800MG	N21179 002	JUL 12, 2000	APR	CAHN
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>A>		GENZYME	400MG	N21179 001	JUL 12, 2000	APR	CAHN
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>A>	+		800MG	N21179 002	JUL 12, 2000	APR	CAHN
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SIROLIMUS

SOLUTION; ORAL

RAPAMUNE

+	WYETH PHARMS INC	1MG/ML	N21083 001	SEP 15, 1999	MAR	CAHN
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TABLET; ORAL

	WYETH PHARMS INC	1MG	N21110 001	AUG 25, 2000	MAR	CRLD
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+		2MG	N21110 002	AUG 22, 2002	MAR	NEWA
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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

@ BIO TECH GEN

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

&gt;A&gt; BERLEX LABS

40MG

N21151 006 APR 02, 2003 APR NEWA

&gt;A&gt;

60MG

N21151 007 APR 02, 2003 APR NEWA

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

AB AEGIS PHARMS

EQ 10MG BASE

N76398 001 MAR 31, 2003 MAR NEWA

AB AEGIS PHARMS

EQ 20MG BASE

N76398 002 MAR 31, 2003 MAR NEWA

AB ANDRX PHARMS

EQ 10MG BASE

N76179 001 FEB 20, 2003 FEB NEWA

AB ANDRX PHARMS

EQ 20MG BASE

N76179 002 FEB 20, 2003 FEB NEWA

AB BARR

EQ 10MG BASE

N70929 001 FEB 20, 2003 FEB NEWA

AB BARR

EQ 20MG BASE

N70929 002 FEB 20, 2003 FEB NEWA

AB IVAX PHARMS

EQ 10MG BASE

N75740 001 FEB 20, 2003 FEB NEWA

AB IVAX PHARMS

EQ 20MG BASE

N75740 002 FEB 20, 2003 FEB NEWA

AB MYLAN

EQ 10MG BASE

N74732 002 FEB 20, 2003 FEB NEWA

AB MYLAN

EQ 20MG BASE

N74732 001 FEB 20, 2003 FEB NEWA

&gt;A&gt; AB PHARMACHEMIE

EQ 10MG BASE

N74539 001 MAR 31, 2003 APR CAHN

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 ROXANE

EQ 20MG BASE

N76027 002 FEB 20, 2003 FEB NEWA

&gt;A&gt; AB TEVA

EQ 10MG BASE

N74504 001 APR 28, 2003 APR NEWA

>D>	AB	EQ 10MG BASE	N74539 001	MAR 31, 2003	APR	CAHN
	AB	EQ 10MG BASE	N74539 001	MAR 31, 2003	MAR	NEWA
	AB	EQ 10MG BASE	N75797 001	FEB 20, 2003	FEB	NEWA
>A>	AB	EQ 20MG BASE	N74504 002	APR 28, 2003	APR	NEWA

TECHNETIUM TC-99M MEDRONATE KIT

INJECTABLE; INJECTION

TECHNISCAN MDP KIT

AP +	DRAXIMAGE	N/A	N18035 001		MAR	CRLD
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TESTOSTERONE

GEL; TOPICAL

ANDROGEL

>D>	+	UNIMED PHARMS	1%	N21015 001	FEB 28, 2000	APR	CTEC
>A>	BX +		1%	N21015 001	FEB 28, 2000	APR	CTEC
		TESTIM					
>D>	+	AUXILIUM A2	1%	N21454 001	OCT 31, 2002	APR	CTEC
>A>	BX +		1%	N21454 001	OCT 31, 2002	APR	CTEC

THALIDOMIDE

CAPSULE; ORAL

THALOMID

CELGENE

+

100MG

200MG

N20785 002	JAN 17, 2003	JAN	NEWA
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	BARR	EQ 2MG BASE	N76371 001	APR 09, 2003	APR	NEWA
>A>	AB		EQ 4MG BASE	N76371 002	APR 09, 2003	APR	NEWA
	AB	MYLAN	EQ 2MG BASE	N76354 001	MAR 28, 2003	MAR	NEWA
	AB		EQ 4MG BASE	N76354 002	MAR 28, 2003	MAR	NEWA

TRAMADOL HYDROCHLORIDE

TABLET; ORAL

TRAMADOL HCL

AB	IVAX PHARMS	50MG	N75963 001	JUL 03, 2002	MAR	CAHN
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TRIAMCINOLONE ACETONIDE

LOTION; TOPICAL

TRIAMCINOLONE ACETONIDE

>A>	AT	ALTANA	0.025%	N40467 001	APR 21, 2003	APR	NEWA
>A>	AT		0.1%	N40467 002	APR 21, 2003	APR	NEWA

UREA, C-13

FOR SOLUTION; ORAL

PYLORI-CHEK BREATH TEST

@	DEVICES	100MG/VIAL	N20900 001	FEB 04, 1999	MAR	CAHN
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VENLAFAXINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

EFFEXOR XR

	WYETH PHARMS INC	EQ 37.5MG BASE	N20699 001	OCT 20, 1997	MAR	CAHN
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		EQ 75MG BASE	N20699 002	OCT 20, 1997	MAR	CRLD
--	--	--------------	------------	--------------	-----	------

@		EQ 100MG BASE	N20699 003	OCT 20, 1997	MAR	CAHN
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+		EQ 150MG BASE	N20699 004	OCT 20, 1997	MAR	CRLD
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TABLET; ORAL

EFFEXOR

@	WYETH PHARMS INC	EQ 12.5MG BASE	N20151 001	DEC 28, 1993	MAR	CAHN
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		EQ 25MG BASE	N20151 002	DEC 28, 1993	MAR	CRLD
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		EQ 37.5MG BASE	N20151 006	DEC 28, 1993	MAR	CAHN
--	--	----------------	------------	--------------	-----	------

		EQ 50MG BASE	N20151 003	DEC 28, 1993	MAR	CAHN
--	--	--------------	------------	--------------	-----	------

		EQ 75MG BASE	N20151 004	DEC 28, 1993	MAR	CAHN
--	--	--------------	------------	--------------	-----	------

+		EQ 100MG BASE	N20151 005	DEC 28, 1993	MAR	CAHN
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VINORELBINE TARTRATE

INJECTABLE; INJECTION

NAVELBINE

AP	+	GLAXOSMITHKLINE	EQ 10MG BASE/ML	N20388 001	DEC 23, 1994	FEB	CFTG
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VINORELBINE TARTRATE

AP		GENSIA SICOR PHARMS	EQ 10MG BASE/ML	N76028 001	FEB 03, 2003	FEB	NEWA
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ZOLEDRONIC ACID

INJECTABLE; IV (INFUSION)

ZOMETA

+	NOVARTIS	EQ 4MG BASE/5ML	N21223 002	MAR 07, 2003	MAR	NEWA
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ALUMINUM HYDROXIDE; MAGNESIUM TRISILICATE

TABLET, CHEWABLE; ORAL

FOAMICON

NOVARTIS

80MG;20MG

N72687 001 JUN 28, 1989 MAR CAHN

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

PSEUDOEPHEDRINE HCL AND CHLORPHENIRAMINE MALEATE

@ CENT PHARMS

8MG;120MG

N19428 001 AUG 02, 1988 MAR DISC

CIMETIDINE

TABLET; ORAL

CIMETIDINE

@ LEK PHARMS

100MG

N75122 001 JUN 19, 1998 MAR CAHN

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

>D> SCHERING

1MG/ML

N20641 002 NOV 27, 2002 APR CRLD

>A> +

1MG/ML

N20641 002 NOV 27, 2002 APR CRLD

1MG/ML

N20641 002 NOV 27, 2002 MAR NEWA

TABLET; ORAL

>D> SCHERING

10MG

N19658 002 NOV 27, 2002 APR CRLD

>A> +

10MG

N19658 002 NOV 27, 2002 APR CRLD

10MG

N19658 002 NOV 27, 2002 MAR NEWA

LORATADINE

GENEVA PHARMS

10MG

N75209 001 JAN 21, 2003 JAN NEWA

TABLET, ORALLY DISINTEGRATING; ORAL

ALAVERT

>D> + WYETH CONS

10MG

N21375 001 DEC 19, 2002 APR CRLD

>A>

10MG

N21375 001 DEC 19, 2002 APR CRLD

CLARITIN REDITABS

>D> SCHERING

10MG

N20704 002 NOV 27, 2002 APR CRLD

>A> +

10MG

N20704 002 NOV 27, 2002 APR CRLD

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

>D>	SCHERING	5MG;120MG	N19670 002	NOV 27, 2002	APR	CRLD
>A>	+	5MG;120MG	N19670 002	NOV 27, 2002	APR	CRLD
		5MG;120MG	N19670 002	NOV 27, 2002	MAR	NEWA
	CLARITIN-D 24 HOUR					
>D>	SCHERING	10MG;240MG	N20470 002	NOV 27, 2002	APR	CRLD
>A>	+	10MG;240MG	N20470 002	NOV 27, 2002	APR	CRLD
		10MG;240MG	N20470 002	NOV 27, 2002	MAR	NEWA
	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
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PERMETHRIN

LOTION; TOPICAL

NIX

+	INSIGHT PHARMS	1%	N19918 001	MAY 02, 1990	MAR	CAHN
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**DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE  
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST**

**CUMULATIVE SUPPLEMENT NUMBER 4 APRIL '03**

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**NO APRIL 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

April 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
4,5-dibromorhodamine 123 Theralux Irradiation Device	DD: 4/10/2003 MA:	Treatment of chronic myelogenous leukemia	Celmed BioSciences Inc. 2310 boul Alfred-Nobel 2310 boul Alfred-Nobel Saint-Laurent, Quebec Canada H4S 2A4
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. 126 East Lincoln Ave. Rahway NJ 07065-0900
alteplase Activase	DD: 1/27/2003 MA:	Treatment of intraventricular hemorrhage associated with intracerebral hemorrhage	Daniel F. Hanley, MD Johns Hopkins University 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

## Orphan Products Designations and Approvals List

April 2003

antisense 20-mer phosphorothioate oligonucleotide [complementary to the coding region of R2 component of the human ribonucleotide reductase mRNA] GTI-2040	DD: 3/12/2003  MA: MA:	Treatment for renal cell carcinoma	Lorus Therapeutics, Inc 2 Meridan Road  Toronto, Ontario M9W4Z7 CANADA
arsenic trioxide  Trisenox	DD: 5/13/2003  MA:	Treatment of chronic lymphocytic leukemia	Cell Therapeutics, Inc. 501 Elliott avenue West 501 Elliott avenue West Suite 400 Seattle WA 98119
bifidobacterium longum infantis 35624	DD: 1/16/2003  MA:	Treatment of pediatric Crohn's disease	Alimentary Health Limited Guardwell, Kinsale County Cork, Ireland
bortezomib VELCADE	DD: 1/15/2003  MA:	To treat multiple myeloma	Millennium Pharmaceuticals, Inc. 75 Sidney Street Cambridge MA 02139
Capsaicin	DD: 5/2/2003  MA:	Treatment of painful HIV-associated neuropathy	NeurogesX, Inc. San Carlos Business Park 981F Industrial Road San Carols CA 94070-4117
cinacalcet	DD: 5/12/2003  MA:	Treatment of hypercalcemia in patients with parathyroid carcinoma	Amgen, Inc.  One Amgen Center Drive Thousand Oaks CA 91320-1799
dextran 1	DD: 3/21/2003  MA:	Treatment of cystic fibrosis	BCY LifeSciences Inc. 160 Eglinton Ave. East Suite 600 Toronto, Ontario M4P 3B5
DHA-paclitaxel  Taxoprexin	DD: 5/1/2003  MA:	Treatment of adenocarcinoma of the stomach or lower esophagus	Protarga, Inc. 2200 Renaissance Boulevard 2200 Renaissance Boulevard Suite 450 King of Prussia PA 19406
Human Anti-tumor Necrosis factor alpha monoclonal antibody	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 Parkway Malvern PA 19355-1307
infliximab Remicade	DD: 5/6/2003  MA:	Treatment of giant cell arteritis	Centocor, Inc. 200 Great Valley Parkway Malvern PA 19355-1307
INGN 201 ADVEXIN	DD: 1/27/2003 MA: MA:	Treatment of head and neck cancer	Introgen Therapeutics, Inc.  2250 Holcombe Blvd

## Orphan Products Designations and Approvals List

April 2003

			Houston TX 77030
iron(III)-hexacyanoferrate(II)	DD: 5/1/2003	Treatment of patients with known or suspected internal contamination with radioactive or non-radioactive cesium or thallium	Heyl Chemisch-Pharmzeutische Fabrik GMBH & Co, KG Goerzallee 253 Goerzallee 253 D-14167 Berlin, Federal Republic of Germany
Radiogardase-Cs / Antidotum	MA: MA:		
Mafosfamide	DD: 1/21/2003	Treatment of neoplastic meningitis	Baxter Oncology GmbH (formerly ASTA Medica Oncology) Daimlerstrasse 40 60314 Frankfurt/Main Germany
	MA:		
MaxAdFVIII	DD: 3/3/2003	Treatment of Hemophilia A	GenStar Therapeutics Corporation 10865 Altman Row Suite 200 San Diego CA 92121-1113
	MA:		
motexafin gadolinium	DD: 1/27/2003	For use in conjunction with whole brain radiation for the treatment of brain metastases arising from solid tumors	Pharmacyclics, Inc. 999 East Arques Avenue 999 East Arques Avenue Sunnyvale CA 94085-4521
Xcytrin	MA: MA:		
polyinosinic-polycytidilic acid	DD: 3/3/2003	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., NW 3203 Cleveland Ave., NW Washington DC 20008-3450
Poly-ICLC	MA: MA:		
recombinant adeno-associated virus alpha 1-antitrypsin vector rAAV-AAT	DD: 1/27/2003	Treatment of alpha1-antitrypsin deficiency	Applied Genetic Technologies Corp. 12085 Research Drive  Suite 110 Alachua FL 32615
	MA: MA:		
recombinant inhibitor of human plasma kallikrein	DD: 2/4/2003	Treatment of angioedema	Dyax Corp 300 Technology Square Cambridge MA 02139
	MA:		
Recombinant T-cell receptor	DD: 5/2/2003	Treatment of multiple sclerosis patients who are both HLA-DR2 positive and glycoprotein residues 35-55 autoreactive to myelin oligodendrocyte	Virogenomics, Inc. 9020 SW Washington Square Road Suite 380  Tigard, OR 97223-4332
	MA: MA:		
repertaxin	DD: 1/27/2003	Prevention of delayed graft function in solid organ transplant	Dompe s.p.a. Via Campo di Pile 67100 - L'Aquila  Italy
	MA:		
resiniferatoxin	DD: 5/13/2003	Treatment of intractable pain at end-stage disease	Andrew J. Mannes, Md Bldg 10/Rm 2N236 - DASS/PPCS/NIDCR/NIH 10 Convent Drive Bethesda MD 20892
	MA:		
Ribavirin USP	DD: 4/4/2003	Treatment of chronic hepatitis C in	Schering Corporation

## Orphan Products Designations and Approvals List

April 2003

REBETOL	MA:	pediatric patients	2000 Galloping Hill Road 2000 Galloping Hill Road Kenilworth NJ 07033
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
Tretinoin	DD: 4/11/2003	Treatment of T-cell non-Hodgkin's lymphoma	Antigenics, Inc. 34 Commerce Way 34 Commerce Way Woburn MA 01801
ATRA-IV	MA:		

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

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NO APRIL 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>		5034394	DEC 18, 2011			
>ADD>	ABACAVIR SULFATE; ZIAGEN	5034394*PED	JUN 18, 2012			
>ADD>	ABACAVIR SULFATE; ZIAGEN	5034394	DEC 18, 2011			
>ADD>		5034394*PED	JUN 18, 2012			
020213 001	ACETYLCHOLINE CHLORIDE; MIOCHOL-E	6261546	APR 29, 2019			
020899 001	ALBUMIN HUMAN; OPTISON	5573751	APR 25, 2012		U-506	
		5529766	JUN 25, 2013		U-505	
		5558094	FEB 28, 2012		U-505	
		5358941	DEC 02, 2012			
		4621077	AUG 06, 2007		U-114	I-309 SEP 29, 2003
		5681590	DEC 02, 2012			MAR 29, 2004
	ALENDRONATE SODIUM; FOSAMAX	5849726	JUN 06, 2015		U-303	
		6008207	JUN 06, 2015			
		6090410	DEC 02, 2012		U-114	
		6194004	DEC 02, 2012			
		4621077*PED	FEB 06, 2008		U-114	
		5358941*PED	JUN 02, 2013			
		5681590*PED	JUN 02, 2013			
		5849726*PED	DEC 06, 2015		U-303	
		6008207*PED	DEC 06, 2015			
		6090410*PED	JUN 02, 2013			
		6194004*PED	JUN 02, 2013			
		5358941	DEC 02, 2012		U-114	
	ALENDRONATE SODIUM; FOSAMAX	4621077	AUG 06, 2007			
		5681590	DEC 02, 2012			
		5849726	JUN 06, 2015			
		6008207	JUN 06, 2015		U-303	
		6090410	DEC 02, 2012			
		4621077*PED	FEB 06, 2008		U-114	
		5358941*PED	JUN 02, 2013			
		5681590*PED	JUN 02, 2013			
		5849726*PED	DEC 06, 2015		U-303	
		6008207*PED	JUN 06, 2015			
		6090410*PED	JUN 02, 2013			
		5358941	DEC 02, 2012		U-114	
		4621077	AUG 06, 2007			
		5681590	DEC 02, 2012			
		5849726	JUN 06, 2015			
		6008207	JUN 06, 2015		U-303	
		6090410	DEC 02, 2012			
		4621077*PED	FEB 06, 2008		U-114	
		5358941*PED	JUN 02, 2013			
		5681590*PED	JUN 02, 2013			
		5849726*PED	DEC 06, 2015		U-303	
		6008207*PED	JUN 06, 2015			
		6090410*PED	JUN 02, 2013			
020560 003	ALENDRONATE SODIUM; FOSAMAX	5358941	DEC 02, 2012		U-114	
>ADD>		4621077	AUG 06, 2007			
>ADD>		5681590	DEC 02, 2012			
>ADD>		5849726	JUN 06, 2015			
>ADD>		6008207	JUN 06, 2015		U-303	
>ADD>		6090410	DEC 02, 2012			
>ADD>		4621077*PED	FEB 06, 2008		U-114	
>ADD>		5358941*PED	JUN 02, 2013			
>ADD>		5681590*PED	JUN 02, 2013			
>ADD>		5849726*PED	DEC 06, 2015		U-303	
>ADD>		6008207*PED	JUN 06, 2015			
>ADD>		6090410*PED	JUN 02, 2013			
>ADD>		5358941	DEC 02, 2012		U-114	
>ADD>		4621077	AUG 06, 2007			
>ADD>		5681590	DEC 02, 2012			
>ADD>		5849726	JUN 06, 2015			
>ADD>		6008207	JUN 06, 2015		U-303	
>ADD>		6090410	DEC 02, 2012			
>ADD>		4621077*PED	FEB 06, 2008		U-114	
>ADD>		5358941*PED	JUN 02, 2013			
>ADD>		5681590*PED	JUN 02, 2013			
>ADD>		5849726*PED	DEC 06, 2015		U-303	
>ADD>		6008207*PED	JUN 06, 2015			
>ADD>		6090410*PED	JUN 02, 2013			

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

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>		6015801	U-353 NS	NS	OCT 20, 2003
>ADD>		4621077	U-114	D-61	OCT 20, 2003
>ADD>	ALENDRONATE SODIUM; FOSAMAX	5358941		D-62	OCT 20, 2003
>ADD>		5681590		PED	APR 20, 2004
>ADD>		5849726		PED	APR 20, 2004
>ADD>		6008207		PED	APR 20, 2004
>ADD>		6090410		PED	APR 20, 2004
>ADD>		5994329			
>ADD>		6225294			
>ADD>		4621077*PED			
>ADD>		5358941*PED			
>ADD>		5681590*PED			
>ADD>		5849726*PED			
>ADD>		5994329*PED			
>ADD>		6008207*PED			
>ADD>		6015801*PED			
>ADD>		6090410*PED			
>ADD>		6225294*PED			
>ADD>		6015801	U-353 NS	NS	OCT 20, 2003
>ADD>		4621077	U-114	D-61	OCT 20, 2003
>ADD>	ALENDRONATE SODIUM; FOSAMAX	5358941		D-62	OCT 20, 2003
>ADD>		5681590		PED	APR 20, 2004
>ADD>		5849726		PED	APR 20, 2004
>ADD>		5994329		PED	APR 20, 2004
>ADD>		6008207		PED	APR 20, 2004
>ADD>		6015801			
>ADD>		6090410			
>ADD>		6225294			
>ADD>		4621077*PED			
>ADD>		5358941*PED			
>ADD>		5681590*PED			
>ADD>		5849726*PED			
>ADD>		5994329*PED			
>ADD>		6008207*PED			
>ADD>		6015801*PED			
>ADD>		6090410*PED			
>ADD>		6225294*PED			
021434 001	ALPRAZOLAM; XANAX XR	5424471			JUL 31, 2012
021434 002	ALPRAZOLAM; XANAX XR	5954703			OCT 31, 2017
021434 003	ALPRAZOLAM; XANAX XR	6322819			OCT 21, 2018
021434 004	ALPRAZOLAM; XANAX XR	6322819			OCT 21, 2018
020221 002	AMIFOSTINE; ETHYOL				
020965 001	AMINOLEVULINIC ACID HYDROCHLORIDE; LEVULIAN				
021303 001	AMPHETAMINE ASPARTATE; ADDERALL XR 10				
021303 006	AMPHETAMINE ASPARTATE; ADDERALL XR 15				

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/PEX EXCL EXPIRES	EXCLUS CODE	EXCLUS EXPIRES
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		
040422 005	AMPHETAMINE ASPARTATE; DEXTROAMP SACCHARATE			PC	SEP 15, 2003
040422 006	AMPHETAMINE ASPARTATE; DEXTROAMP SACCHARATE			PC	SEP 15, 2003
040422 007	AMPHETAMINE ASPARTATE; DEXTROAMP SACCHARATE			PC	SEP 15, 2003
021549 001	APREPITANT; EMEND	5719147	JUN 29, 2012	NCE	MAR 26, 2008
>ADD>		5538982	JUL 23, 2013		
>ADD>		6048859	JUN 29, 2012		
>ADD>		6096742	JUL 01, 2018		
>ADD>		6235735	JUN 29, 2012		
>ADD>		5719147	JUN 29, 2012		
>ADD>		5538982	JUL 23, 2013		
>ADD>		6048859	JUN 29, 2012		
>ADD>		6096742	JUL 01, 2018		
>ADD>		6235735	JUN 29, 2012		
>ADD>		4734416	MAR 29, 2005		
021436 001	ARIPIPIRAZOLE; ABILIFY	5006528	OCT 20, 2009		
021436 002	ARIPIPIRAZOLE; ABILIFY	4734416	MAR 29, 2005		
021436 003	ARIPIPIRAZOLE; ABILIFY	5006528	OCT 20, 2009		
021436 004	ARIPIPIRAZOLE; ABILIFY	4734416	MAR 29, 2005		
021436 005	ARIPIPIRAZOLE; ABILIFY	5006528	OCT 20, 2009		
021436 006	ARIPIPIRAZOLE; ABILIFY	4734416	MAR 29, 2005		
021411 001	ATOMOXETINE HYDROCHLORIDE; STRATTERA	5006528	OCT 20, 2009		
021411 002	ATOMOXETINE HYDROCHLORIDE; STRATTERA	5658590	JAN 11, 2015	U-494 NCE	NOV 26, 2007
021411 003	ATOMOXETINE HYDROCHLORIDE; STRATTERA	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
021411 005	ATOMOXETINE HYDROCHLORIDE; STRATTERA	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
075766 001	CALCITRIOL; CALCITRIOL	5658590*PED	JUL 11, 2015	U-494 PED	MAY 26, 2008
075766 002	CALCITRIOL; CALCITRIOL	5658590	JAN 11, 2015	U-494 NCE	NOV 26, 2007
075823 001	CALCITRIOL; CALCITRIOL	5658590*PED	JUL 11, 2015	U-494 PED	MAY 26, 2008
>ADD>		5658590	JAN 11, 2015	U-494 NCE	NOV 26, 2007

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>						
075823 002	CALCITRIOL; CALCITRIOL	4789724	AUG 01, 2006		PC	SEP 17, 2003
075836 001	CALCITRIOL; CALCITRIOL	4757128	AUG 01, 2006		PC	SEP 17, 2003
075836 002	CALCITRIOL; CALCITRIOL				PC	SEP 17, 2003
020637 001	CARMUSTINE; GLIADEL				I-382	FEB 25, 2006
020297 001	CARVEDILOL; COREG				I-388	MAR 27, 2006
020297 002	CARVEDILOL; COREG				I-388	MAR 27, 2006
020297 003	CARVEDILOL; COREG				I-388	MAR 27, 2006
020297 004	CARVEDILOL; COREG				I-388	MAR 27, 2006
021150 001	CETIRIZINE HYDROCHLORIDE; ZYRTEC-D 12 HOUR	4525358	JUN 25, 2007	U-295		
>ADD>		4525358*PED	DEC 25, 2007	U-295		
019758 001	CICLOPIROX; LOPROX	6469009	JUL 13, 2019	U-295		
019758 002	CICLOPIROX; LOPROX	6469009*PED	JAN 13, 2020	U-295		
021141 001	CIPROFLOXACIN; CIPRO XR	6489329	APR 08, 2016			
017821 001	CLOZAPINE; CLOZARIL	6489329*PED	OCT 08, 2016			
021165 001	CLOZAPINE; CLOZARIL					
>ADD>						
021159 001	COLESEVELAM HYDROCHLORIDE; WELCHOL	4670444	DEC 09, 2003		NDF	FEB 28, 2006
021473 001	COLESEVELAM HYDROCHLORIDE; WELCHOL	6504030	JUN 10, 2019		NDF	DEC 13, 2005
020839 001	DESLOMATADINE; CLARINEX					
019758 001	DILTIAZEM HYDROCHLORIDE; CARDIZEM LA	6066678	JUN 10, 2014	U-323	I-380	DEC 18, 2005
019758 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM LA	4659716	APR 21, 2004		I-380	DEC 18, 2005
021141 001	DILTIAZEM HYDROCHLORIDE; CARDIZEM LA	4863931	SEP 15, 2008			
017821 001	DILTIAZEM HYDROCHLORIDE; CARDIZEM LA	4804666	FEB 14, 2006	U-427	D-78	FEB 03, 2006
021165 001	DILTIAZEM HYDROCHLORIDE; CARDIZEM LA	5595997	DEC 30, 2014	U-427	NCE	DEC 21, 2006
021141 001	DESLOMATADINE; CLARINEX	6100274	JUL 07, 2019	U-429	PED	JUN 21, 2007
017821 001	DESLOMATADINE; CLARINEX	4659716*PED	OCT 21, 2004			
021165 001	DESLOMATADINE; CLARINEX	4804666*PED	AUG 14, 2006			
017821 001	DESLOMATADINE; CLARINEX	4863931*PED	MAR 15, 2009			
021165 001	DESLOMATADINE; CLARINEX	5595997*PED	JUN 30, 2015			
021312 001	DESLOMATADINE; CLARINEX	6100274*PED	JAN 07, 2020			
>ADD>						
021392 001	DILTIAZEM HYDROCHLORIDE; CARDIZEM LA	5288505	JUN 26, 2011		NCE	DEC 21, 2006
021392 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM LA	5529791	JUN 25, 2013		PED	JUN 21, 2007
021392 003	DILTIAZEM HYDROCHLORIDE; CARDIZEM LA	5288505	JUN 26, 2011		NDF	FEB 06, 2006
021392 004	DILTIAZEM HYDROCHLORIDE; CARDIZEM LA	5529791	JUN 25, 2013		NDF	FEB 06, 2006
021392 005	DILTIAZEM HYDROCHLORIDE; CARDIZEM LA	5288505	JUN 26, 2011		NDF	FEB 06, 2006
>ADD>		5288505	JUN 25, 2013		NDF	FEB 06, 2006
>ADD>		5529791	JUN 25, 2013		NDF	FEB 06, 2006
>ADD>		5288505	JUN 26, 2011		NDF	FEB 06, 2006
>ADD>		5529791	JUN 25, 2013		NDF	FEB 06, 2006
>ADD>		5288505	JUN 26, 2011		NDF	FEB 06, 2006
>ADD>		5529791	JUN 25, 2013		NDF	FEB 06, 2006
>ADD>		5288505	JUN 26, 2011		NDF	FEB 06, 2006
>ADD>		5529791	JUN 25, 2013		NDF	FEB 06, 2006
>ADD>		5288505	JUN 26, 2011		NDF	FEB 06, 2006
>ADD>		5529791	JUN 25, 2013		NDF	FEB 06, 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
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	U-138		
		6037353	MAR 14, 2017			
		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 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	U-138		
		6037353	MAR 14, 2017			
		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
021077 003	FLUTICASON 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			
		4335121*	MAY 14, 2004	U-386		
019957 001	FLUTICASON PROPIONATE;CUTIVATE	4335121	NOV 14, 2003			
019958 001	FLUTICASON PROPIONATE;CUTIVATE	4335121*	MAY 14, 2004			
020121 001	FLUTICASON PROPIONATE;FLONASE	4335121	NOV 14, 2003			
020548 001	FLUTICASON PROPIONATE;FLOVENT	4335121*	MAY 14, 2004			
020548 002	FLUTICASON PROPIONATE;FLOVENT	4335121	NOV 14, 2003			
020548 003	FLUTICASON PROPIONATE;FLOVENT	4335121*	MAY 14, 2004		D-76	MAY 23, 2005
020549 001	FLUTICASON PROPIONATE;FLOVENT	4335121	NOV 14, 2003		PED	NOV 23, 2005
020549 002	FLUTICASON PROPIONATE;FLOVENT	4335121*	MAY 14, 2004			
020549 003	FLUTICASON PROPIONATE;FLOVENT	4335121	NOV 14, 2003			
020833 001	FLUTICASON PROPIONATE;FLOVENT DISKUS 50	4335121*	MAY 14, 2004			
020833 002	FLUTICASON PROPIONATE;FLOVENT DISKUS 100	4335121	NOV 14, 2003			
020833 003	FLUTICASON PROPIONATE;FLOVENT DISKUS 250	4335121*	MAY 14, 2004			
020261 001	FLUVASTATIN SODIUM;LESCOL	5354772	OCT 11, 2011			
020261 002	FLUVASTATIN SODIUM;LESCOL	5354772	OCT 11, 2011			
021192 001	FLUVASTATIN SODIUM;LESCOL XL	5354772	OCT 11, 2011			
020831 001	FORMOTEROL FUMARATE;FORADIL	6488027	OCT 11, 2011			
019915 002	FOSINOPRIL SODIUM;MONOPRIL	4337201	MAR 08, 2019			
		5006344	DEC 04, 2002			
		5006344*	JUL 10, 2009			
		5006344*	JAN 10, 2010			
019915 003	FOSINOPRIL SODIUM;MONOPRIL	4337201*	JUN 04, 2003			
		4337201	DEC 04, 2002			
		5006344	JUL 10, 2009			
		5006344*	JAN 10, 2010			
		4337201*	JUN 04, 2003			
		4337201*	DEC 04, 2002			
		5006344*	JUL 10, 2009			
		5006344*	JAN 10, 2010			
		4337201*	JUN 04, 2003			
		4337201*	DEC 04, 2002			
		5006344*	JUL 10, 2009			
		5006344*	JAN 10, 2010			
		4337201*	JUN 04, 2003			
		4337201*	DEC 04, 2002			
		5006344*	JUL 10, 2009			
		5006344*	JAN 10, 2010			
		4337201*	JUN 04, 2003			
		4337201*	DEC 04, 2002			
		5006344*	JUL 10, 2009			
		5006344*	JAN 10, 2010			
		4337201*	JUN 04, 2003			
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		5006344*	JUL 10, 2009			
		5006344*	JAN 10, 2010			
		4337201*	JUN 04, 2003			
		4337201*	DEC 04, 2002			
		5006344*	JUL 10, 2009			
		5006344*	JAN 10, 2010			
		4337201*	JUN 04, 2003			
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		5006344*	JUL 10, 2009			
		5006344*	JAN 10, 2010			
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		5006344*	JAN 10, 2010			
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		4337201*	DEC 04, 2002			
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		5006344*	JAN 10, 2010			
		4337201*	JUN 04, 2003			
		4337201*	DEC 04, 2002			
		5006344*	JUL 10, 2009			
		5006344*	JAN 10, 2010			
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		4337201*	DEC 04, 2002			
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		5006344*	JAN 10, 2010			
		4337201*	JUN 04, 2003			
		4337201*	DEC 04, 2002			
		5006344*	JUL 10, 2009			
		5006344*	JAN 10, 2010			
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		4337201*	DEC 04, 2002			
		5006344*	JUL 10, 2009			
		5006344*	JAN 10, 2010			
		4337201*	JUN 04, 2003			
		4337201*	DEC 04, 2002			
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		4337201*	JUN 04, 2003			
		4337201*	DEC 04, 2002			
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		5006344*	JAN 10, 2010			
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		5006344*	JUL 10, 2009			
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		4337201*	JUN 04, 2003			
		4337201*	DEC 04, 2002			
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		5006344*	JAN 10, 2010			
		4337201*	JUN 04, 2003			
		4337201*	DEC 04, 2002			
		5006344*	JUL 10, 2009			
		5006344*	JAN 10, 2010			
		4337201*	JUN 04, 2003			
		4337201*	DEC 04, 2002			
		5006344*	JUL 10, 2009			
		5006344*	JAN 10, 2010			
		4337201*	JUN 04, 2003			
		4337201*	DEC 04, 2002			
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		4337201*	JUN 04, 2003			
		4337201*	DEC 04, 2002			
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		4337201*	DEC 04, 2002			
		5006344*	JUL 10, 2009			
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		4337201*	DEC 04, 2002			
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		5006344*	JAN 10, 2010			
		4337201*	JUN 04, 2003			
		4337201*	DEC 04, 2002			
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		4337201*	DEC 04, 2002			
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		4337201*	DEC 04, 2002			
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		5006344*	JUL 10, 2009			
		5006344*	JAN 10, 2010			
		4337201*	JUN 04, 2003			
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		5006344*	JAN 10, 2010			
		4337201*	JUN 04, 2003			
		4337201*	DEC 04, 2002			
		5006344*	JUL 10, 2009			
		5006344*	JAN 10, 2010			
		4337201*	JUN 04, 2003			
		4337201*	DEC 04, 2002			
		5006344*	JUL 10, 2009			
		5006344*	JAN 10, 2010			
		4337201*	JUN 04, 2003			
		4337201*	DEC 04, 2002			
		5006344*	JUL 10, 2009			
		5006344*	JAN 10, 2010			
		4337201*	JUN 04, 2003			
		4337201*	DEC 04, 2002			
		5006344*	JUL 10,			

PRESCRIPTION AND OTC DRUG PRODUCT  
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL USE EXPIRES	EXCLUS CODE	EXCLUS EXPIRES
019915 004	FOSINOPRIL SODIUM; MONOPRIL	4337201	DEC 04, 2002		
		5006344	JUL 10, 2009		
		5006344*PED	JAN 10, 2010		
020286 001	FOSINOPRIL SODIUM; MONOPRIL-HCT	4337201*PED	JUN 04, 2003		
		4337201	DEC 04, 2002		
		5006344	JUL 10, 2009		
		5006344*PED	JAN 10, 2010		
020286 002	FOSINOPRIL SODIUM; MONOPRIL-HCT	4337201*PED	JUN 04, 2003		
		4337201	DEC 04, 2002		
		5006344	JUL 10, 2009		
		5006344*PED	JAN 10, 2010		
		4337201*PED	JUN 04, 2003		
>ADD>	GATIFLOXACIN; ZYMAR			NDF	MAR 28, 2006
>ADD>				NCE	DEC 17, 2004
>ADD>	GEMIFLOXACIN MESYLATE; FACTIVE			NCE	APR 04, 2008
020329 001	GLIPIZIDE; GLUCOTROL XL	6262071	SEP 21, 2019		
		6331550	SEP 21, 2019		
		6340689	SEP 14, 2019		
		6455540	SEP 21, 2019		
		5091190	SEP 05, 2009	U-111	
		5545413	JUL 21, 2008	U-111	
020329 002	GLIPIZIDE; GLUCOTROL XL	5091190	SEP 05, 2009	U-111	
		5545413	JUL 21, 2008	U-111	
020329 003	GLIPIZIDE; GLUCOTROL XL	4612008	SEP 16, 2003		
		5024843	SEP 05, 2009		
		5082668	SEP 16, 2003		
		5091190	SEP 05, 2009		
		5545413	JUL 21, 2008		
		5591454	JAN 07, 2014		
		6372252	APR 28, 2020	U-489	
		6248726	JUN 19, 2018	U-495	
021282 002	GUAIFENESIN; MUCINEX	4761237	AUG 02, 2005		
021321 001	ICODEXTRIN; EXTRANEAL	4886789	DEC 12, 2006		
		6077836	JUN 20, 2017		
		5521184	MAY 28, 2013		
		5521184	MAY 28, 2013		
		4364921	MAR 06, 2005		
		4364921	MAR 06, 2005		
		5047407*PED	MAY 17, 2010		
		5047407	NOV 17, 2009		
		5047407	NOV 17, 2009		
		5047407*PED	MAY 17, 2010		
		5047407	NOV 17, 2009		
		5047407*PED	MAY 17, 2010		
>ADD>	LAMOTRIGINE; LAMICTAL			NCE	MAY 10, 2006
>ADD>				NCE	MAY 10, 2006
021588 001	IMATINIB MESYLATE; GLEEVEC				
021588 002	IMATINIB MESYLATE; GLEEVEC				
021425 001	IOPROMIDE; ULTRAVIST (PHARMACY				
021425 002	IOPROMIDE; ULTRAVIST (PHARMACY				
020857 001	LAMIVUDINE; COMBIVIR				
021003 001	LAMIVUDINE; EPIVIR-HBV				
021004 001	LAMIVUDINE; EPIVIR-HBV				
>ADD>	LAMOTRIGINE; LAMICTAL				

PRESCRIPTION AND OTC DRUG PRODUCT  
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PEX EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	LAMOTRIGINE; LAMICTAL	5362755	NOV 08, 2011	U-332	I-387	JAN 17, 2006
>ADD>	LAMOTRIGINE; LAMICTAL	6555581	FEB 15, 2022		I-387	JAN 17, 2006
>ADD>	LAMOTRIGINE; LAMICTAL	6555581	FEB 15, 2022		I-387	JAN 17, 2006
>ADD>	LAMOTRIGINE; LAMICTAL	6555581	FEB 15, 2022		I-387	JAN 17, 2006
>ADD>	LAMOTRIGINE; LAMICTAL	6555581	FEB 15, 2022		I-387	JAN 17, 2006
>ADD>	LAMOTRIGINE; LAMICTAL CD	6555581	FEB 15, 2022		I-387	JAN 17, 2006
>ADD>	LAMOTRIGINE; LAMICTAL CD	6555581	FEB 15, 2022		I-387	JAN 17, 2006
>ADD>	LAMOTRIGINE; LAMICTAL CD	6555581	FEB 15, 2022		I-387	JAN 17, 2006
>ADD>	LAMOTRIGINE; LAMICTAL CD	6555581	FEB 15, 2022		I-387	JAN 17, 2006
>ADD>	LEVALBUTEROL HYDROCHLORIDE; XOPENEX	5362755	NOV 08, 2011	U-332	NP	FEB 13, 2006
>ADD>	LEVOTHYROXINE SODIUM; LEVOXYL	6555581	FEB 15, 2022			
>ADD>	LEVOTHYROXINE SODIUM; LEVOXYL	6555581	FEB 15, 2022			
>ADD>	LEVOTHYROXINE SODIUM; LEVOXYL	6555581	FEB 15, 2022			
>ADD>	LEVOTHYROXINE SODIUM; LEVOXYL	6555581	FEB 15, 2022			
>ADD>	LEVOTHYROXINE SODIUM; LEVOXYL	6555581	FEB 15, 2022			
>ADD>	LEVOTHYROXINE SODIUM; LEVOXYL	6555581	FEB 15, 2022			
>ADD>	LEVOTHYROXINE SODIUM; LEVOXYL	6555581	FEB 15, 2022			
>ADD>	LEVOTHYROXINE SODIUM; LEVOXYL	6555581	FEB 15, 2022			
>ADD>	LEVOTHYROXINE SODIUM; LEVOXYL	6555581	FEB 15, 2022			
>ADD>	LEVOTHYROXINE SODIUM; LEVOXYL	6555581	FEB 15, 2022			
>ADD>	LEVOTHYROXINE SODIUM; LEVOXYL	6555581	FEB 15, 2022			
>ADD>	LEVOTHYROXINE SODIUM; LEVOXYL	6555581	FEB 15, 2022			
>ADD>	LEVOTHYROXINE SODIUM; LEVOXYL	6555581	FEB 15, 2022			
>ADD>	LIDOCAINE; LIDODERM	5589180	MAR 17, 2009	U-485		
>ADD>	LIDOCAINE; LIDODERM	5411738	MAY 02, 2012	U-485		
>ADD>	LIDOCAINE; LIDODERM	5827529	OCT 27, 2015	U-486		
>ADD>	LIDOCAINE; LIDODERM	5709869	MAR 17, 2009	U-485		
>ADD>	LIDOCAINE; LIDODERM	5601838	MAY 02, 2012	U-488		
>ADD>	LINEZOLID; ZYVOX	6521651	NOV 01, 2017		NPP	DEC 19, 2005
>ADD>	LINEZOLID; ZYVOX				NPP	DEC 19, 2005
>ADD>	LINEZOLID; ZYVOX				NPP	DEC 19, 2005
>ADD>	LINEZOLID; ZYVOX				NPP	DEC 19, 2005
>ADD>	LOPINAVIR; KALETRA				PC	JUL 21, 2003
>ADD>	LOPINAVIR; KALETRA				PC	AUG 09, 2003
>ADD>	LOPINAVIR; KALETRA				PC	JUL 30, 2003
>ADD>	LOPINAVIR; KALETRA				PC	JUL 30, 2003
>ADD>	LOSARTAN POTASSIUM; COZAAR	5210079	MAY 11, 2010	U-496	I-383	SEP 17, 2005
>ADD>	LOSARTAN POTASSIUM; COZAAR	5210079	MAY 11, 2010	U-496	I-383	SEP 17, 2005
>ADD>	LOSARTAN POTASSIUM; COZAAR	5210079	MAY 11, 2010	U-496	I-383	SEP 17, 2005
>ADD>	LOSARTAN POTASSIUM; COZAAR	5210079	MAY 11, 2010	U-496	I-383	SEP 17, 2005
>ADD>	METFORMIN HYDROCHLORIDE; AVANDAMET				NCE	MAY 25, 2004
>ADD>	METFORMIN HYDROCHLORIDE; AVANDAMET				NCE	MAY 25, 2004
>ADD>	METFORMIN HYDROCHLORIDE; AVANDAMET				NCE	MAY 25, 2004
>ADD>	METFORMIN HYDROCHLORIDE; AVANDAMET				NCE	MAY 25, 2004
>ADD>	MIRTAZAPINE; MIRTAZAPINE				PC	JUN 16, 2003
>ADD>	MIRTAZAPINE; MIRTAZAPINE				PC	JUN 16, 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 USE EXPIRES	EXCLUS CODE	EXCLUS EXPIRES
021438 002	PROPRANOLOL HYDROCHLORIDE; INNOPRAN XL	6500454	DEC 31, 2022	NP	MAR 12, 2006
020903 001	RIBAVIRIN; REBETOL	6524570	NOV 01, 2016	U-499	
		6524570*PED	MAY 01, 2017	U-499	
>ADD>	RISPERIDONE; RISPERDAL			M-15	MAR 03, 2005
>ADD>	RISPERIDONE; RISPERDAL			M-15	MAR 03, 2005
>ADD>	RISPERIDONE; RISPERDAL			M-15	MAR 03, 2005
021444 002	RISPERIDONE; RISPERDAL			M-15	MAR 03, 2005
021444 003	RISPERIDONE; RISPERDAL			M-15	MAR 03, 2005
021071 002	ROSIGLITAZONE MALEATE; AVANDIA			I-384	FEB 27, 2006
021071 003	ROSIGLITAZONE MALEATE; AVANDIA			I-384	FEB 27, 2006
021071 004	ROSIGLITAZONE MALEATE; AVANDIA			I-384	FEB 27, 2006
019414 001	RUBIDIUM CHLORIDE RB-82; CARDIOGEN-82	4562829	MAY 01, 2004	U-503	
019839 001	SERTRALINE HYDROCHLORIDE; ZOLOFT			I-261	FEB 07, 2006
019839 002	SERTRALINE HYDROCHLORIDE; ZOLOFT			I-261	FEB 07, 2006
019839 003	SERTRALINE HYDROCHLORIDE; ZOLOFT			I-261	FEB 07, 2006
019839 004	SERTRALINE HYDROCHLORIDE; ZOLOFT			I-261	FEB 07, 2006
019839 005	SERTRALINE HYDROCHLORIDE; ZOLOFT			I-261	FEB 07, 2006
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		
019766 001	SIMVASTATIN; ZOCOR			I-390	APR 16, 2006
019766 002	SIMVASTATIN; ZOCOR			I-390	APR 16, 2006
019766 003	SIMVASTATIN; ZOCOR			I-390	APR 16, 2006
019766 004	SIMVASTATIN; ZOCOR			I-390	APR 16, 2006
019766 005	SIMVASTATIN; ZOCOR			I-390	APR 16, 2006
021083 001	SIROLIMUS; RAPAMUNE			I-386	APR 11, 2006
021110 001	SIROLIMUS; RAPAMUNE			I-386	APR 11, 2006
021110 002	SIROLIMUS; RAPAMUNE			I-386	APR 11, 2006
>ADD>		5100899	JUN 06, 2009	U-290	SEP 15, 2004
>ADD>		5212155	MAY 18, 2010	U-291	APR 11, 2006
>ADD>		5308847	MAY 03, 2011	U-292	APR 11, 2006
>ADD>		5403833	APR 04, 2012	U-293	APR 11, 2006
>ADD>		5989591	MAR 11, 2018		
020280 007	SOMATROPIN RECOMBINANT; GENOTROPIN			ODE	OCT 31, 2004
020280 001	SOMATROPIN RECOMBINANT; GENOTROPIN			ODE	OCT 31, 2004
020280 002	SOMATROPIN RECOMBINANT; GENOTROPIN			ODE	OCT 31, 2004
020280 003	SOMATROPIN RECOMBINANT; GENOTROPIN			ODE	OCT 31, 2004
020280 005	SOMATROPIN RECOMBINANT; GENOTROPIN			ODE	OCT 31, 2004
020280 008	SOMATROPIN RECOMBINANT; GENOTROPIN			ODE	OCT 31, 2004
020280 009	SOMATROPIN RECOMBINANT; GENOTROPIN			ODE	OCT 31, 2004
020280 010	SOMATROPIN RECOMBINANT; GENOTROPIN			ODE	OCT 31, 2004
020280 011	SOMATROPIN RECOMBINANT; GENOTROPIN			ODE	OCT 31, 2004
020280 012	SOMATROPIN RECOMBINANT; GENOTROPIN			ODE	OCT 31, 2004
020280 013	SOMATROPIN RECOMBINANT; GENOTROPIN			ODE	OCT 31, 2004
021148 001	SOMATROPIN RECOMBINANT; NORDITROPIN	5633352	MAY 27, 2014		
>ADD>		5849700	DEC 15, 2015	U-340	
>ADD>		5849704	DEC 15, 2015		

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 USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>		5633352			
>ADD>	SOMATROPIN RECOMBINANT; NORDITROPIN	5849700	U-340		
>ADD>		5633352			
>ADD>	SOMATROPIN RECOMBINANT; NORDITROPIN	5849700	U-340		
>ADD>		5849704			
>ADD>	SOTALOL HYDROCHLORIDE; BETAPACE AF			NP	FEB 22, 2003
>ADD>				PED	AUG 22, 2003
>ADD>	STAVUDINE; ZERIT	4978655			
>ADD>		4978655*PED			
>ADD>	STAVUDINE; ZERIT XR				
>ADD>		4978655	U-248		
>ADD>	STAVUDINE; ZERIT XR				
>ADD>		4978655*PED	U-248		
>ADD>	STAVUDINE; ZERIT XR				
>ADD>		4978655	U-248		
>ADD>	STAVUDINE; ZERIT XR				
>ADD>		4978655*PED	U-248		
>ADD>	STAVUDINE; ZERIT XR				
>ADD>		4978655	U-248		
>ADD>	TERBINAFINE HYDROCHLORIDE; LAMISIL				
>ADD>		6121314	U-248		
>ADD>	TERBINAFINE HYDROCHLORIDE; LAMISIL AT				
>ADD>		6121314	U-502		
>ADD>	TESTOSTERONE; ANDRODERM				
>ADD>		4983395	U-504		
>ADD>		4983395			
>ADD>	TESTOSTERONE; ANDRODERM				
>ADD>		5152997	U-490		
>ADD>		5164190			
>ADD>		4849224			
>ADD>		4852294			
>ADD>		4849224			
>ADD>		4852294			
>ADD>		4863970			
>ADD>		4983395			
>ADD>		5152997			
>ADD>		5164190			
>ADD>	TESTOSTERONE; TESTIM				
>ADD>	TOPIRAMATE; TOPAMAX	4513006		NP	OCT 31, 2005
>ADD>		4513006			
>ADD>	TOPIRAMATE; TOPAMAX				
>ADD>		4513006			
>ADD>	TOPIRAMATE; TOPAMAX				
>ADD>		4513006			
>ADD>	TOPIRAMATE; TOPAMAX				
>ADD>		4513006			
>ADD>	TOPIRAMATE; TOPAMAX				
>ADD>		4513006			
>ADD>	TOPIRAMATE; TOPAMAX SPRINKLE				
>ADD>		4513006			
>ADD>	TRAVOPROST; TRAVATAN				
>ADD>		6531141			
>ADD>	TRETINOIN; RENOVA				
>ADD>	VALACYCLOVIR HYDROCHLORIDE; VALTRES				
>ADD>				M-23	FEB 13, 2006
>ADD>				I-381	SEP 09, 2005
>ADD>				I-389	APR 01, 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 EXPIRES	EXCL USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020550 002	VALACYCLOVIR HYDROCHLORIDE; VALTREX					
020699 001	VENLAFAXINE HYDROCHLORIDE; EFFEXOR XR				I-381	SEP 09, 2005
020699 002	VENLAFAXINE HYDROCHLORIDE; EFFEXOR XR				I-389	APR 01, 2006
020699 003	VENLAFAXINE HYDROCHLORIDE; EFFEXOR XR				I-261	FEB 11, 2006
020699 004	VENLAFAXINE HYDROCHLORIDE; EFFEXOR XR				I-261	FEB 11, 2006
020552 001	VERAPAMIL HYDROCHLORIDE; COVERA-HS	4612008	SEP 16, 2003		I-261	FEB 11, 2006
		6146662	AUG 14, 2007	U-366		
020552 002	VERAPAMIL HYDROCHLORIDE; COVERA-HS	4612008	SEP 16, 2003			
		6146662	AUG 14, 2007	U-366		

>ADD>

## 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  
 I-384 USE IN COMBINATION WITH INSULIN FOR THE TREATMENT OF PATIENTS WITH TYPE 2 DIABETES  
 I-385 MODIFICATION OF THE INDICATION FOR COMMUNITY ACQUIRED PNEUMONIA TO ADD "INCLUDING PENICILLIN-RESISTANT STRAINS, MIC PENICILLIN $\geq$ 2MCG/ML" TO STREPTOCOCCUS PNEUMONIAE  
 I-386 RAPAMUNE (SIROLIMUS) WITHIN AN IMMUNOSUPPRESSIVE REGIMEN THAT WOULD ALLOW FOR THE WITHDRAWAL OF CYCLOSPORINE 2 TO 4 MONTHS AFTER RENAL TRANSPLANTATION IN PATIENTS CONSIDERED AT LOW TO MODERATE IMMUNOLOGIC RISK FOR RENAL TRANSPLANT REJECTION  
 I-387 ADJUNCTIVE THERAPY OF PARTIAL SEIZURES IN PEDIATRIC PATIENTS GREATER THAT OR EQUAL TO 2 YEARS OF AGE  
 I-388 TREATMENT OF PATIENTS WITH LEFT VENTRICULAR DYSFUNCTION FOLLOWING MYOCARDIAL INFARCTION  
 I-389 SUPPRESSION OF RECURRENT GENITAL HERPES IN HIV-INFECTED INDIVIDUALS  
 I-390 USE IN PTS AT HIGH RISK CORONARY EVENTS DUE TO EXISTING CORONARY HEART DISEASE, DIABETES, PERIPHERAL VESSEL DISEASE, STROKE HISTORY, OTHER CV DISEASE TO REDUCE RISK TOTAL MORTALITY BY REDUCING CORONARY DEATH, REDUCE NONFATAL MI & STROKE.....

### 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
- U-508 METHOD OF RELEASING 17-BETA OESTRADIOL PRECURSOR IN A SUBSTANTIALLY ZERO ORDER PATTERN FOR AT LEAST THREE WEEKS

