

**CUMULATIVE
SUPPLEMENT 5
MAY 2003**



APPROVED DRUG PRODUCTS

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

23rd EDITION

Department of Health and Human Services

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

2003

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& MCNAMARA, P.C.
WASHINGTON, DC

DEMCO

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23RD EDITION

Cumulative Supplement 5

May 2003

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

23rd EDITION

CUMULATIVE SUPPLEMENT 5
May 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have never been marketed, are for exportation, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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)

BAYER CORP
(BAYER)
BAYER CORP CONSUMER CARE DIV
(BAYER CORP CONSUMER)
BAYER CORP PHARMACEUTICALS DIV
(BAYER)
LEK SERVICES INC
(LEK SVCS)
LEK LJUBLJANA PHARMACEUTICAL AND CHEMICAL CO
(LEK LJUBLJANA)
LEK PHARMACEUTICAL AND CHEMICAL DD
(LEK PHARM)
SIDMAK LABORATORIES INC
(SIDMAK LABS)
SYNTEX (USA) INC LLC
(SYNTEX USA INC)

BAYER PHARMACEUTICALS CORP
(BAYER PHARMS)
BAYER CORP CONSUMER CARE LLC
(BAYER)
BAYER PHARMACEUTICALS CORP
(BAYER PHARMS)
LEK PHARMACEUTICALS DD
(LEK PHARM DD)
LEK PHARMACEUTICALS DD
(LEK PHARM DD)
LEK PHARMACEUTICALS DD
(LEK PHARM DD)
PLIVA INC
(PLIVA)
ROCHE PALO ALTO LLC
(ROCHE PALO)

1.3 NITROGLYCERIN, FILM, EXTENDED RELEASE; TRANSDERMAL 23RD ANNUAL EDITION

The *Approved Drug Products with Therapeutic Equivalence Evaluations 23rd 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

<u>CATEGORIES COUNTED</u>	<u>COUNTS CUMULATIVE BY QUARTER</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	106 (1.0%)			
NEW MOLECULAR ENTITIES	6			
APPROVED				
NUMBER OF APPLICANTS	598			

¹Amino 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.

PRESCRIPTION DRUG PRODUCT LIST - 23RD EDITION
RX DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 5 - MAY 2003

1-1

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

BUTALBITAL, APAP, AND CAFFEINE

>A> AB AXIOM PHARM 325MG;50MG;40MG

N89536 001 FEB 16, 1988 MAY CAHN

>D> AB HALSEY 325MG;50MG;40MG

N89536 001 FEB 16, 1988 MAY CAHN

FIORICET

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

>A> AA ABLE 500MG;7.5MG

N40490 001 MAY 21, 2003 MAY NEWA

>A> AA ANDRX PHARMS 500MG;5MG

N40493 001 MAY 28, 2003 MAY NEWA

>A> AA 660MG;10MG

N40495 001 MAY 28, 2003 MAY NEWA

>A> AA 750MG;7.5MG

N40494 001 MAY 28, 2003 MAY NEWA

>A> AA AXIOM PHARM 500MG;5MG

N40236 001 SEP 25, 1997 MAY CAHN

>A> AA 650MG;10MG

N40240 001 NOV 26, 1997 MAY CAHN

>A> AA 650MG;7.5MG

N40240 002 NOV 26, 1997 MAY CAHN

>A> AA 750MG;7.5MG

N40236 002 SEP 25, 1997 MAY CAHN

>D> AA HALSEY 500MG;5MG

N40236 001 SEP 25, 1997 MAY CAHN

>D> AA 650MG;10MG

N40240 001 NOV 26, 1997 MAY CAHN

>D> AA 650MG;7.5MG

N40240 002 NOV 26, 1997 MAY CAHN

>D> AA 750MG;7.5MG

N40236 002 SEP 25, 1997 MAY CAHN

AA MIKART 325MG;7.5MG

N40432 001 JAN 22, 2003 JAN NEWA

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

CAPSULE; ORAL

OXYCODONE AND ACETAMINOPHEN

>A>	AA	AXIOM PHARM	500MG;5MG	N40219 001	JAN 22, 1998	MAY	CAHN
>D>	AA	HALSEY	500MG;5MG	N40219 001	JAN 22, 1998	MAY	CAHN

ACYCLOVIR

CAPSULE; ORAL

ACYCLOVIR

AB	AAIPHARMA	200MG	N74833 001	APR 22, 1997	APR	CAHN
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ALBUTEROL SULFATE

SOLUTION; INHALATION

ALBUTEROL SULFATE

AN	NOVEX	EQ 0.5% BASE	N76391 001	APR 01, 2003	APR	NEWA
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ALFENTANIL HYDROCHLORIDE

INJECTABLE; INJECTION

ALFENTA

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

TABLET; ORAL

AXERT

		JANSSEN ORTHO	EQ 6.25MG BASE	N21001 001	MAY 07, 2001	APR	CAHN
	+		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
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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

AB		GENEVA PHARMS	100MG	N71293 001	FEB 18, 1987	APR	CAHN
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AMCINONIDE

CREAM; TOPICAL

AMCINONIDE

>A>	AB	ALTANA	0.1%	N76065 001	MAY 15, 2003	MAY	NEWA
>D>	AT	TARO PHARM INDS	0.1%	N76229 001	MAY 31, 2002	MAY	CTEC
>A>	AB		0.1%	N76229 001	MAY 31, 2002	MAY	CTEC
	AT		0.1%	N76229 001	MAY 31, 2002	APR	NEWA

CYCLOCORT

>D>	AT +	FUJISAWA HLTHCARE	0.1%	N18116 002		MAY	CTEC
>A>	AB +		0.1%	N18116 002		MAY	CTEC
	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

	AP	APOTEX	50MG/ML	N76394 001	APR 25, 2003	APR	NEWA
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CORDARONE

	AP +	WYETH PHARMS INC	50MG/ML	N20377 001	AUG 03, 1995	MAR	CAHN
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TABLET; ORAL

	AB	WYETH PHARMS INC	200MG	N18972 001	DEC 24, 1985	MAR	CAHN
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AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL

ETRAFON 2-10

a SCHERING 10MG;2MG

N14713 007		MAR	DISC
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ETRAFON 2-25

a SCHERING 25MG;2MG

N14713 004		MAR	DISC
------------	--	-----	------

ETRAFON-FORTE

a SCHERING 25MG;4MG

N14713 006		MAR	DISC
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AMMONIUM LACTATE

CREAM; TOPICAL

AMMONIUM LACTATE

	AB	TARO	EQ 12% BASE	N75883 001	APR 10, 2003	APR	NEWA
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AMOXICILLIN; CLARITHROMYCIN; LANSOPRAZOLE

>A> CAPSULE, TABLET, CAPSULE, DELAYED REL PELLETS; ORAL

>A> PREVPAC

>A> + TAP PHARM 500MG;500MG;30MG

N50757 001	DEC 02, 1997	MAY	CDFR
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>D> CAPSULE, TABLET, CAPSULE, EXTENDED RELEASE; ORAL

>D> PREVPAC

>D> + TAP PHARM 500MG;500MG;30MG

N50757 001	DEC 02, 1997	MAY	CDFR
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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
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	AB		400MG/5ML;EQ 57MG BASE/5ML	N65132 002	MAR 19, 2003	MAR	NEWA
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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						
>A> AB WATSON LABS	1.25MG;1.25MG;1.25MG;1.25MG	N40456 001	MAY 06, 2003	MAY	NEWA		
>A> AB	2.5MG;2.5MG;2.5MG;2.5MG	N40456 002	MAY 06, 2003	MAY	NEWA		
>A> AB	5MG;5MG;5MG;5MG	N40456 003	MAY 06, 2003	MAY	NEWA		
>A> AB	7.5MG;7.5MG;7.5MG;7.5MG	N40456 004	MAY 06, 2003	MAY	NEWA		
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		
SOLUTION; ORAL							
+ GLAXOSMITHKLINE	15MG/ML	N21039 001	APR 15, 1999	MAR	CMFD		

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		
TABLET; ORAL							
AB + WATSON PHARMS	325MG;50MG;40MG	N17534 003	APR 16, 1986	MAR	CAHN		

ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE

CAPSULE; ORAL

FIORINAL W/CODEINE NO 3

AB + WATSON PHARMS 325MG;50MG;40MG;30MG

N19429 003 OCT 26, 1990 MAR CAHN

ASPIRIN; OXYCODONE HYDROCHLORIDE; OXYCODONE TEREPHTHALATE

TABLET; ORAL

OXYCODONE AND ASPIRIN

>A> AA AXIOM PHARM 325MG;4.5MG;0.38MG
 >D> AA HALSEY 325MG;4.5MG;0.38MG

N40260 001 JUL 17, 1998 MAY CAHN

N40260 001 JUL 17, 1998 MAY CAHN

ATOMOXETINE HYDROCHLORIDE

CAPSULE; ORAL

STRATTERA

>D> LILLY 5MG
 >A> @ 5MG

N21411 001 NOV 26, 2002 MAY DISC

N21411 001 NOV 26, 2002 MAY DISC

AZATHIOPRINE

TABLET; ORAL

AZASAN

AB AAIPHARMA LLC 25MG
 50MG
 75MG
 100MG

N75252 002 FEB 03, 2003 FEB NEWA

N75252 001 JUN 07, 1999 FEB NEWA

N75252 003 FEB 03, 2003 FEB NEWA

N75252 004 FEB 03, 2003 FEB NEWA

AZELASTINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

OPTIVAR

+ MEDPOINTE 0.05%

N21127 001 MAY 22, 2000 APR CAHN

BECLOMETHASONE DIPROPIONATE

AEROSOL, METERED; INHALATION

BECLOVENT

@ GLAXOSMITHKLINE 0.042MG/INH

N18153 001 MAR DISC

AEROSOL, METERED; NASAL

BECONASE

@ GLAXOSMITHKLINE 0.042MG/INH

N18584 001 MAR DISC

VANCENASE

@ SCHERING 0.042MG/INH

N18521 001 MAR DISC

BETAMETHASONE

TABLET; ORAL

CELESTONE

@ SCHERING 0.6MG

N12657 003 FEB DISC

BETAMETHASONE DIPROPIONATE

CREAM; TOPICAL

ALPHATREX

>D> AB SAVAGE LABS EQ 0.05% BASE
 >A> AB + EQ 0.05% BASE

N19138 001 JUN 26, 1984 MAY CRLD

N19138 001 JUN 26, 1984 MAY CRLD

>D> DIPROSONE

>D> AB + SCHERING EQ 0.05% BASE

N17536 001 MAY DISC

>A>	@	EQ 0.05% BASE	N17536 001		
	GEL, AUGMENTED; TOPICAL			MAY	DISC
>A>	BETAMETHASONE DIPROPIONATE				
>A>	AB ALTANA	EQ 0.05% BASE	N75276 001	MAY 13, 2003	MAY NEWA
	DIPROLENE				
>D>	+ SCHERING	EQ 0.05% BASE	N19408 002	NOV 22, 1991	MAY CFTG
>A>	AB +	EQ 0.05% BASE	N19408 002	NOV 22, 1991	MAY CFTG
	<u>BISOPROLOL FUMARATE</u>				
	TABLET; ORAL				
	ZEBETA				
AB	WYETH PHARMS INC	5MG	N19982 002	JUL 31, 1992	MAR CAHN
AB +		10MG	N19982 001	JUL 31, 1992	MAR CAHN
	<u>BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE</u>				
	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
>A>	<u>BORTEZOMIB</u>				
>A>	INJECTABLE; INTRAVENOUS				
>A>	VELCADE				
>A>	+ MILLENNIUM PHARMS	3.5MG/VIAL	N21602 001	MAY 13, 2003	MAY NEWA
	<u>BRIMONIDINE TARTRATE</u>				
	SOLUTION/DROPS; OPHTHALMIC				
>A>	BRIMONIDINE TARTRATE				
>A>	+ BAUSCH AND LOMB	0.2%	N76260 001	MAY 28, 2003	MAY NEWA
	<u>BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE</u>				
	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
>A>	<u>BUPIVACAINE HYDROCHLORIDE; LIDOCAINE HYDROCHLORIDE</u>				
>A>	INJECTABLE; INJECTION				
>A>	DUOCAINE				
>A>	+ AMPAHSTAR	0.375% (37.5MG/10ML);1% (100MG/10ML)	N21496 001	MAY 23, 2003	MAY NEWA
	<u>BUSPIRONE HYDROCHLORIDE</u>				
	TABLET; ORAL				
	BUSPIRONE HCL				
AB	EGIS	15MG	N75119 003	JAN 23, 2003	JAN NEWA
	<u>CALCITRIOL</u>				
	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	GENSIA SICOR PHARMS	0.001MG/ML		N75823 001	MAR 31, 2003	MAR	NEWA
AP		0.002MG/ML		N75823 002	MAR 31, 2003	MAR	NEWA

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM SULFATE; POTASSIUM CHLORIDE; SODIUM BICARBONATE;
SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE

INJECTABLE; INTRATHECAL

ELLIOTTS B SOLUTION

>D>	+	ORPHAN MEDCL	0.2MG/ML;0.8MG/ML;0.3MG/ML;0.3MG/ML; ;1.9MG/ML;7.3MG/ML;0.2MG/ML	N20577 001	SEP 27, 1996	MAY	CAHN
>A>	+	QOL MEDCL	0.2MG/ML;0.8MG/ML;0.3MG/ML;0.3MG/ML; ;1.9MG/ML;7.3MG/ML;0.2MG/ML	N20577 001	SEP 27, 1996	MAY	CAHN

CARBINOXAMINE MALEATE

SOLUTION; ORAL

CARBINOXAMINE MALEATE

+	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

+	GLAXOSMITHKLINE	12.5MG	N20297 002	SEP 14, 1995	APR	CRLD
		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

CEFDITOREN PIVOXIL

TABLET; ORAL

SPECTRACEF

>A>	+	PURDUE PHARMA LP	200MG	N21222 001	AUG 29, 2001	MAY	CAHN
>D>	+	TAP PHARM	200MG	N21222 001	AUG 29, 2001	MAY	CAHN

CEFIXIME

FOR SUSPENSION; ORAL

SUPRAX

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

CEFOXITIN SODIUM

INJECTABLE; INJECTION

MEFOXIN IN PLASTIC CONTAINER

+ MERCK EQ 20MG BASE/ML
 + EQ 40MG BASE/ML

N63182 001 JAN 25, 1993 MAR CRLD
 N63182 002 JAN 25, 1993 MAR CRLD

CEFUROXIME AXETIL

TABLET; ORAL

CEFUROXIME AXETIL

AB RANBAXY EQ 125MG BASE
 AB EQ 250MG BASE
 AB EQ 500MG BASE

N65118 001 APR 25, 2003 APR NEWA
 N65118 002 APR 25, 2003 APR NEWA
 N65118 003 APR 25, 2003 APR NEWA

CEPHALOTHIN SODIUM

INJECTABLE; INJECTION

CEPHALOTHIN SODIUM

+ BRISTOL EQ 1GM BASE/VIAL
 + EQ 2GM BASE/VIAL
 + EQ 4GM BASE/VIAL
 KEFLIN
 @ LILLY EQ 1GM BASE/VIAL
 @ EQ 2GM BASE/VIAL
 @ EQ 4GM BASE/VIAL

N62464 001 MAY 07, 1984 MAR CRLD
 N62464 002 MAY 07, 1984 MAR CRLD
 N62464 003 MAY 07, 1984 MAR CRLD

N50482 001 MAR DISC
 N50482 002 MAR DISC
 N50482 003 MAR DISC

CHLORAMPHENICOL

OINTMENT; OPHTHALMIC

CHLORAMPHENICOL

>D> AT ALTANA 1%
 >A> AT + 1%
 >D> CHLOROMYCETIN
 >D> AT + PARKEDALE 1%
 >A> @ 1%
 SOLUTION/DROPS; OTIC
 >D> + PARKEDALE 0.5%
 >A> @ 0.5%

N60133 001 MAY CRLD
 N60133 001 MAY CRLD

N50156 001 MAY DISC
 N50156 001 MAY DISC

N50205 001 MAY DISC
 N50205 001 MAY DISC

CHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL

ALDOCLOR-150

>D> MERCK 150MG;250MG
 >A> @ 150MG;250MG
 >D> ALDOCLOR-250
 >D> + MERCK 250MG;250MG
 >A> @ 250MG;250MG

N16016 001 MAY DISC
 N16016 001 MAY DISC

N16016 002 MAY DISC
 N16016 002 MAY DISC

CHLORTHALIDONE

TABLET; ORAL

THALITONE

>D> BX MONARCH PHARMS 25MG
 >A> @ 25MG

N19574 002 FEB 12, 1992 MAY DISC
 N19574 002 FEB 12, 1992 MAY DISC

<u>CICLOPIROX</u>			
SHAMPOO; TOPICAL			
LOPROX			
	+ MEDICIS	1%	N21159 001 FEB 28, 2003 FEB NEWA
<u>CLADRIBINE</u>			
INJECTABLE; INJECTION			
LEUSTATIN			
AP	+ ORTHO BIOTECH	1MG/ML	N20229 001 FEB 26, 1993 APR CTEC
<u>CLINDAMYCIN HYDROCHLORIDE</u>			
CAPSULE; ORAL			
CLINDAMYCIN HCL			
AB	WATSON LABS	EQ 300MG BASE	N63083 002 MAR 18, 2003 MAR NEWA
<u>CLONAZEPAM</u>			
TABLET, ORALLY DISINTEGRATING; ORAL			
KLONOPIN RAPIDLY DISINTEGRATING			
	ROCHE	0.125MG	N20813 001 DEC 23, 1997 APR CMFD
		0.25MG	N20813 002 DEC 23, 1997 APR CMFD
		0.5MG	N20813 003 DEC 23, 1997 APR CMFD
	+	1MG	N20813 004 DEC 23, 1997 APR CMFD
		2MG	N20813 005 DEC 23, 1997 APR CMFD
<u>COLESTIPOL HYDROCHLORIDE</u>			
TABLET; ORAL			
COLESTID			
>D>	PHARMACIA AND UPJOHN	1GM	N20222 001 JUL 19, 1994 MAY CRLD
>A>	+	1GM	N20222 001 JUL 19, 1994 MAY CRLD
<u>COPPER</u>			
INTRAUTERINE DEVICE; INTRAUTERINE			
COPPER T MODEL TCU 380A			
	+ FEI	309MG/COPPER	N18680 001 NOV 15, 1984 MAR CAHN
<u>CORTISONE ACETATE</u>			
TABLET; ORAL			
CORTISONE ACETATE			
BP	+ PHARMACIA AND UPJOHN	25MG	N08126 001 APR CRLD
CORTONE			
	@ MERCK	25MG	N07750 003 APR DISC
<u>CROMOLYN SODIUM</u>			
SOLUTION/DROPS; OPHTHALMIC			
CROMOPTIC			
>D>	AT	KING PHARMS	N75088 001 APR 27, 1999 MAY DISC
>A>	@		N75088 001 APR 27, 1999 MAY DISC
<u>CYCLOBENZAPRINE HYDROCHLORIDE</u>			
TABLET; ORAL			
FLEXERIL			
AA	MCNEIL CONS SPECT	5MG	N17821 001 MAR CMFD

		5MG	N17821 001	APR	CTEC
<u>CYCLOSPORINE</u>					
CAPSULE; ORAL					
GENGRAF					
AB1	ABBOTT	25MG	N65003 001	MAY 12, 2000	FEB CTNA
BX		50MG	N65003 002	MAY 12, 2000	FEB CTNA
AB1		100MG	N65003 003	MAY 12, 2000	FEB CTNA
EMULSION; OPHTHALMIC					
RESTASIS					
+	ALLERGAN	0.05%	N50790 001	DEC 23, 2002	MAR CMS1
<u>DALFOPRISTIN; QUINUPRISTIN</u>					
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
<u>DEMECLOCYCLINE HYDROCHLORIDE</u>					
TABLET; ORAL					
DECLOMYCIN					
@	WYETH PHARMS INC	75MG	N50261 001		MAR CAHN
		150MG	N50261 002		MAR CAHN
+		300MG	N50261 003		MAR CAHN
<u>DESIRUDIN</u>					
INJECTABLE; SUBCUTANEOUS					
IPRIVASK					
+	AVENTIS PHARMS	15MG/VIAL	N21271 001	APR 04, 2003	APR NEWA
<u>DESMOPRESSIN ACETATE</u>					
SPRAY, METERED; NASAL					
DESMOPRESSIN ACETATE					
>A>	AB + FERRING	0.01MG/SPRAY	N21333 001	SEP 16, 2002	MAY CMS1
>D>	+	0.01MG/SPRAY	N21333 001	SEP 16, 2002	MAY CMS1
<u>DESOGESTREL; ETHINYL ESTRADIOL</u>					
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
<u>DEXAMETHASONE</u>					
ELIXIR; ORAL					
DECADRON					
@	MERCK	0.5MG/5ML	N12376 002		APR DISC
HEXADROL					
AA +	ORGANON	0.5MG/5ML	N12674 001		APR CRLD

DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

DEXAMETHASONE SODIUM PHOSPHATE

AP	AM PHARM	EQ 10MG PHOSPHATE/ML	N40491 001	APR 11, 2003	APR	NEWA
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>D> DEXAMETHASONE SODIUM PHOSPHATE; NEOMYCIN SULFATE

>D> SOLUTION/DROPS; OPHTHALMIC

>D> NEODECADRON

>D>	+	MERCK	EQ 0.1% PHOSPHATE;EQ 3.5MG BASE/ML	N50322 001		MAY	DISC
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>A>	@		EQ 0.1% PHOSPHATE;EQ 3.5MG BASE/ML	N50322 001		MAY	DISC
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DEXTROAMPHETAMINE SULFATE

CAPSULE, EXTENDED RELEASE; ORAL

DEXTROAMPHETAMINE SULFATE

>A>	AB	MALLINCKRODT	5MG	N76353 001	MAY 06, 2003	MAY	NEWA
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>A>	AB		10MG	N76353 002	MAY 06, 2003	MAY	NEWA
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>A>	AB		15MG	N76353 003	MAY 06, 2003	MAY	NEWA
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>D> DICHLORPHENAMIDE

>D> TABLET; ORAL

>D> DARANIDE

>D>	+	MERCK	50MG	N11366 001		MAY	DISC
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>A>	@		50MG	N11366 001		MAY	DISC
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DIGOXIN

TABLET; ORAL

DIGOXIN

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

INJECTABLE; INJECTION

D.H.E. 45

AP	+	XCEL PHARMS	1MG/ML	N05929 001		APR	CFTG
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DIHYDROERGOTAMINE MESYLATE

AP	PADDOCK	1MG/ML	N40475 001	APR 28, 2003	APR	NEWA
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DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

TAZTIA XT

AB4	ANDRX PHARMS	120MG	N75401 001	APR 10, 2003	APR	NEWA
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AB4		180MG	N75401 002	APR 10, 2003	APR	NEWA
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AB4		240MG	N75401 003	APR 10, 2003	APR	NEWA
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AB4		300MG	N75401 004	APR 10, 2003	APR	NEWA
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AB4		360MG	N75401 005	APR 10, 2003	APR	NEWA
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TIAZAC

AB4	+	BIOVAIL	120MG	N20401 001	SEP 11, 1995	APR	CFTG
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AB4	+		180MG	N20401 002	SEP 11, 1995	APR	CFTG
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AB4	+		240MG	N20401 003	SEP 11, 1995	APR	CFTG
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AB4	+		300MG	N20401 004	SEP 11, 1995	APR	CFTG
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AB4	+		360MG	N20401 005	SEP 11, 1995	APR	CFTG
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DILTIAZEM HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

CARDIZEM LA

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

>D> DILTIAZEM MALATE

>D> TABLET, EXTENDED RELEASE; ORAL

>D> TIAMATE

>D>	+	MERCK	EQ 120MG HCL	N20506 001	OCT 04, 1996	MAY	DISC
>A>	@		EQ 120MG HCL	N20506 001	OCT 04, 1996	MAY	DISC
>D>	+		EQ 180MG HCL	N20506 002	OCT 04, 1996	MAY	DISC
>A>	@		EQ 180MG HCL	N20506 002	OCT 04, 1996	MAY	DISC
>D>	+		EQ 240MG HCL	N20506 003	OCT 04, 1996	MAY	DISC
>A>	@		EQ 240MG HCL	N20506 003	OCT 04, 1996	MAY	DISC

DOXAPRAM HYDROCHLORIDE

INJECTABLE; INJECTION

DOPRAM

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

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

CAPSULE; ORAL

DOXYCYCLINE

>A>	AB	AXIOM PHARM	EQ 50MG BASE	N65041 001	APR 28, 2000	MAY	CAHN
>A>	AB		EQ 100MG BASE	N65041 002	APR 28, 2000	MAY	CAHN
>D>	AB	HALSEY	EQ 50MG BASE	N65041 001	APR 28, 2000	MAY	CAHN
>D>	AB		EQ 100MG BASE	N65041 002	APR 28, 2000	MAY	CAHN

DOXYCYCLINE HYCLATE

CAPSULE; ORAL

DOXYCYCLINE HYCLATE

>A>	AB	AXIOM PHARM	EQ 50MG BASE	N61717 001		MAY	CAHN
>A>	AB		EQ 100MG BASE	N61717 002		MAY	CAHN
>D>	AB	HALSEY	EQ 50MG BASE	N61717 001		MAY	CAHN
>D>	AB		EQ 100MG BASE	N61717 002		MAY	CAHN

CAPSULE, COATED PELLETS; ORAL

DORYX

FAULDING

			EQ 75MG BASE	N50582 002	AUG 13, 2001	FEB	NEWA
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INJECTABLE; INJECTION

DOXY 100

+ AM PHARM PARTNERS

			EQ 100MG BASE/VIAL	N62475 001	DEC 09, 1983	MAR	CRLD
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DOXY 200

+ AM PHARM PARTNERS

			EQ 200MG BASE/VIAL	N62475 002	DEC 09, 1983	MAR	CRLD
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DOXYCYCLINE HYCLATE

INJECTABLE; INJECTION

VIBRAMYCIN

@ PFIZER

EQ 100MG BASE/VIAL

N50442 002

MAR DISC

@

EQ 200MG BASE/VIAL

N50442 001

MAR DISC

TABLET; ORAL

DOXYCYCLINE HYCLATE

>A> AB AXIOM PHARM

EQ 100MG BASE

N62269 002 NOV 08, 1982 MAY CAHN

>D> AB HALSEY

EQ 100MG BASE

N62269 002 NOV 08, 1982 MAY CAHN

DOXYCYCLINE HYLATE

>A> @ AXIOM PHARM

EQ 50MG BASE

N62269 003

MAY CAHN

>D> @ HALSEY

EQ 50MG BASE

N62269 003

MAY CAHN

EDROPHONIUM CHLORIDE

INJECTABLE; INJECTION

>D> REVERSOL

>D> AP ORGANON

10MG/ML

N89624 001 MAY 13, 1988 MAY DISC

>A> @

10MG/ML

N89624 001 MAY 13, 1988 MAY 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

ENFUVIRTIDE

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

>A> INJECTABLE; IM-SC

>A> TWINJECT

>A> + HOLLISTER STIER LABS 0.3MG /DELIVERY

N20800 001 MAY 30, 2003 MAY 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
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ERYTHROMYCIN

SOLUTION; TOPICAL

STATICIN

+	WESTWOOD SQUIBB	1.5%	N50526 001		APR	CTEC
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ESMOLOL HYDROCHLORIDE

INJECTABLE; INJECTION

BREVIBLOC DOUBLE STRENGTH IN PLASTIC CONTAINER

+	BAXTER HLTHCARE CORP	2GM/100ML	N19386 005	JAN 27, 2003	MAR	NEWA
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BREVIBLOC IN PLASTIC CONTAINER

+	BAXTER HLTHCARE CORP	1GM/100ML	N19386 004	FEB 16, 2001	MAR	NEWA
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ESTRADIOL ACETATE

INSERT, EXTENDED RELEASE; VAGINAL

FEMRING

GALEN LTD

0.05MG/24HR

N21367 001	MAR 20, 2003	MAR	NEWA
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+		0.1MG/24HR	N21367 002	MAR 20, 2003	MAR	NEWA
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>D> ESTRADIOL CYPIONATE; TESTOSTERONE CYPIONATE

>D> INJECTABLE; INJECTION

>D> DEPO-TESTADIOL

>D> + PHARMACIA AND UPJOHN 2MG/ML;50MG/ML

N17968 001		MAY	WDAG
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>A> @ 2MG/ML;50MG/ML

N17968 001		MAY	WDAG
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ESTRADIOL; NORGESTIMATE

TABLET; ORAL

>D> ORTHO-PREFEST

>D> + KING PHARMS 1MG;1MG;0.09MG

N21040 001	OCT 22, 1999	MAY	CTNA
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>A> PREFEST

>A> + KING PHARMS 1MG;1MG;0.09MG

N21040 001	OCT 22, 1999	MAY	CTNA
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ESTROGENS, CONJUGATED

CREAM; TOPICAL, VAGINAL

PREMARIN

+ WYETH PHARMS INC 0.625MG/GM

N20216 001		MAR	CAHN
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INJECTABLE; INJECTION

+ WYETH PHARMS INC 25MG/VIAL

N10402 001		MAR	CAHN
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TABLET; ORAL

WYETH PHARMS INC

0.3MG

N04782 003		MAR	CAHN
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+ 0.625MG

N04782 004		MAR	CAHN
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0.9MG

N04782 005	JAN 26, 1984	MAR	CAHN
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+ 1.25MG

N04782 001		MAR	CAHN
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2.5MG

N04782 002		MAR	CAHN
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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
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ESTROGENS, CONJUGATED; MEDROXYPROGESTERONE ACETATE

TABLET; ORAL-28

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

ETHACRYNIC ACID

TABLET; ORAL

EDECIN

>D>	MERCK	25MG	N16092 001		MAY	CRLD
>A>	+	25MG	N16092 001		MAY	CRLD
>D>	+	50MG	N16092 002		MAY	DISC
>A>	@	50MG	N16092 002		MAY	DISC

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						
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
LEVONORGESTREL AND ETHINYL ESTRADIOL						
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						
FEMHRT						
>A>	+	GALEN CHEM	0.005MG;1MG	N21065 002	OCT 15, 1999	MAY CAHN
>D>	+	PFIZER PHARMS	0.005MG;1MG	N21065 002	OCT 15, 1999	MAY CAHN
TABLET; ORAL-21						
ESTROSTEP 21						
	ⓐ	GALEN CHEM	0.02MG;0.03MG;0.035MG;1MG;1MG;1MG	N20130 001	OCT 09, 1996	APR CAHN
>A>		JUNEL 1.5/30				
>A>	AB	BARR	0.03MG;1.5MG	N76381 001	MAY 30, 2003	MAY NEWA
>A>		JUNEL 1/20				
>A>	AB	BARR	0.02MG;1MG	N76380 001	MAY 30, 2003	MAY NEWA
LOESTRIN 21 1.5/30						
>D>	+	GALEN CHEM	0.03MG;1.5MG	N17875 001		MAY CFTG
>A>	AB	+	0.03MG;1.5MG	N17875 001		MAY CFTG
	+		0.03MG;1.5MG	N17875 001		APR CAHN
LOESTRIN 21 1/20						
>D>	+	GALEN CHEM	0.02MG;1MG	N17876 001		MAY CFTG
>A>	AB	+	0.02MG;1MG	N17876 001		MAY CFTG
	+		0.02MG;1MG	N17876 001		APR CAHN
TABLET; ORAL-28						
ESTROSTEP FE						
+		GALEN CHEM	0.02MG;0.03MG;0.035MG;1MG;1MG;1MG	N20130 002	OCT 09, 1996	APR CAHN
LOESTRIN FE 1.5/30						
AB	+	GALEN CHEM	0.03MG;1.5MG	N17355 001		APR CAHN
LOESTRIN FE 1/20						
AB	+	GALEN CHEM	0.02MG;1MG	N17354 001		APR CAHN

ETHINYL ESTRADIOL; NORGESTREL

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

ETHINYL ESTRADIOL; NORGESTREL

TABLET; ORAL-28

OGESTREL 0.5/50-28

AB	WATSON LABS	0.05MG;0.5MG	N75406 002	DEC 15, 1999	FEB	CAHN
	OVRAL-28					
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
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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

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

LODINE XL

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
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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)					
a ABBOTT	67MG	N19304 002	FEB 09, 1998	MAR	DISC
a	134MG	N19304 003	JUN 30, 1999	MAR	DISC
a	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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FLUOCINONIDE

CREAM; TOPICAL

FLUOCINONIDE

>D>	AB	ALPHARMA US PHARM	0.05%	N73085 001	FEB 14, 1992	MAY	CTEC
>A>	AB1		0.05%	N73085 001	FEB 14, 1992	MAY	CTEC
>D>	AB	FOUGERA	0.05%	N73030 001	OCT 17, 1994	MAY	CTEC
>A>	AB1		0.05%	N73030 001	OCT 17, 1994	MAY	CTEC
>D>	AB	TARO	0.05%	N19117 001	JUN 26, 1984	MAY	CTEC
>A>	AB1		0.05%	N19117 001	JUN 26, 1984	MAY	CTEC
>D>	AB		0.05%	N71500 001	JUN 10, 1987	MAY	CTEC
>A>	AB1		0.05%	N71500 001	JUN 10, 1987	MAY	CTEC
>D>	AB	TEVA	0.05%	N72488 001	FEB 06, 1989	MAY	CTEC
>A>	AB1		0.05%	N72488 001	FEB 06, 1989	MAY	CTEC

FLUOCINONIDE EMULSIFIED BASE

>D>	AB	ALPHARMA US PHARM	0.05%	N74204 001	JUN 13, 1995	MAY	CTEC
>A>	AB2		0.05%	N74204 001	JUN 13, 1995	MAY	CTEC
>D>	AB	DRAXIS HLTH	0.05%	N72494 001	JAN 19, 2089	MAY	CTEC
>A>	AB2		0.05%	N72494 001	JAN 19, 2089	MAY	CTEC
>D>	AB	TEVA	0.05%	N72490 001	FEB 07, 1989	MAY	CTEC
>A>	AB2		0.05%	N72490 001	FEB 07, 1989	MAY	CTEC

FLUOCINONIDE

CREAM; TOPICAL

LIDEX

>D>	AB +	MEDICIS	0.05%	N16908 002		MAY	CTEC
>A>	AB1 +		0.05%	N16908 002		MAY	CTEC
LIDEX-E							
>D>	AB	MEDICIS	0.05%	N16908 003		MAY	CRLD
>A>	AB2 +		0.05%	N16908 003		MAY	CRLD

FLUORESCEIN SODIUM

INJECTABLE; INJECTION

FUNDUSCEIN-25

@ NOVARTIS	25%	N17869 001		JAN	DISC
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FLUPHENAZINE DECANOATE

INJECTABLE; INJECTION

FLUPHENAZINE DECANOATE

>D>	AO	KING PHARMS	25MG/ML	N74966 001	APR 16, 1998	MAY	DISC
>A>	@		25MG/ML	N74966 001	APR 16, 1998	MAY	DISC

FLURANDRENOLIDE

LOTION; TOPICAL

CORDRAN

>D>	AT +	OCLASSEN	0.05%	N13790 001		MAY	CTEC
>A>	+		0.05%	N13790 001		MAY	CTEC

FLUTAMIDE

CAPSULE; ORAL

FLUTAMIDE

>A>	AB	GENPHARM	125MG	N76224 001	MAY 09, 2003	MAY	NEWA
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FLUVOXAMINE MALEATE

TABLET; ORAL

FLUVOXAMINE MALEATE

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

FOLIC ACID

INJECTABLE; INJECTION

FOLVITE

AP +	WYETH PHARMS INC	5MG/ML	N05897 008		MAR	CAHN
TABLET; ORAL						
@	WYETH PHARMS INC	1MG	N05897 004		MAR	CAHN

GALANTAMINE HYDROBROMIDE

TABLET; ORAL

REMINYL

+	JANSSEN PHARMA	EQ 4MG BASE	N21169 001	FEB 28, 2001	APR	CRLD
		EQ 12MG BASE	N21169 003	FEB 28, 2001	APR	CRLD

GATIFLOXACIN

INJECTABLE; INJECTION

TEQUIN

+	BRISTOL MYERS SQUIBB	EQ 2MG /ML(200MG/100ML)	N21062 001	DEC 17, 1999	APR	CRLD
+		EQ 2MG /ML(400MG/200ML)	N21062 002	DEC 17, 1999	APR	CRLD
+		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
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>A> GEFITINIB

>A> TABLET; ORAL

>A> IRESSA

>A>	+	ASTRAZENECA	250MG	N21399 001	MAY 05, 2003	MAY	NEWA
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GEMIFLOXACIN MESYLATE

TABLET; ORAL

FACTIVE

>A>	+	GENESOF PHARMS	EQ 320MG BASE	N21158 001	APR 04, 2003	MAY	CAHN
>D>	+	LG LIFE	EQ 320MG BASE	N21158 001	APR 04, 2003	MAY	CAHN
	+		EQ 320MG BASE	N21158 001	APR 04, 2003	APR	NEWA

GEMTUZUMAB OZOGAMICIN

INJECTABLE; INJECTION

MYLOTARG

+	WYETH PHARMS INC	5MG/VIAL	N21174 001	MAY 17, 2000	MAR	CAHN
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GENTAMICIN SULFATE

CREAM; TOPICAL

GARAMYCIN

@	SCHERING	EQ 0.1% BASE	N60462 001		FEB	DISC
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GENTAMICIN SULFATE

AT	+	FOUGERA	EQ 0.1% BASE	N62531 001	JUL 05, 1984	FEB	CRLD
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OINTMENT; OPHTHALMIC

GARAMYCIN

@	SCHERING	EQ 0.3% BASE	N50425 001		APR	DISC
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GENTAMICIN SULFATE

+	AKORN	EQ 0.3% BASE	N64093 001	AUG 31, 1995	APR	CRLD
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GLIMEPIRIDE

TABLET; ORAL

AMARYL

+	AVENTIS PHARMS	1MG	N20496 001	NOV 30, 1995	JAN	CRLD
		4MG	N20496 003	NOV 30, 1995	JAN	CRLD

GONADORELIN HYDROCHLORIDE

INJECTABLE; INJECTION

FACTREL

>A>	+	BAXTER HLTHCARE CORP	EQ 0.1MG BASE/VIAL	N18123 001	SEP 30, 1982	MAY	CAHN
>A>	@		EQ 0.2MG BASE/VIAL	N18123 002	SEP 30, 1982	MAY	CAHN
>A>	@		EQ 0.5MG BASE/VIAL	N18123 003	SEP 30, 1982	MAY	CAHN
>D>	+	WYETH AYERST	EQ 0.1MG BASE/VIAL	N18123 001	SEP 30, 1982	MAY	CAHN

>D>	@	EQ 0.2MG BASE/VIAL	N18123 002	SEP 30, 1982	MAY	CAHN
>D>	@	EQ 0.5MG BASE/VIAL	N18123 003	SEP 30, 1982	MAY	CAHN

>D> GREPAFLOXACIN HYDROCHLORIDE

>D> TABLET; ORAL

>D> RAXAR

>D> OTSUKA

		EQ 200MG BASE	N20695 001	NOV 06, 1997	MAY	DISC
>A>	@	EQ 200MG BASE	N20695 001	NOV 06, 1997	MAY	DISC
>D>		EQ 400MG BASE	N20695 002	MAY 14, 1998	MAY	DISC
>A>	@	EQ 400MG BASE	N20695 002	MAY 14, 1998	MAY	DISC
>D>	+	EQ 600MG BASE	N20695 003	MAY 14, 1998	MAY	DISC
>A>	@	EQ 600MG BASE	N20695 003	MAY 14, 1998	MAY	DISC

HALOPERIDOL DECANOATE

INJECTABLE; INJECTION

HALOPERIDOL DECANOATE

>D>	AO	KING PHARMS	EQ 50MG BASE/ML	N75176 001	FEB 09, 2000	MAY	DISC
>A>		@	EQ 50MG BASE/ML	N75176 001	FEB 09, 2000	MAY	DISC
>D>	AO		EQ 100MG BASE/ML	N75176 002	FEB 09, 2000	MAY	DISC
>A>		@	EQ 100MG BASE/ML	N75176 002	FEB 09, 2000	MAY	DISC

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN LOCK FLUSH

>A>	@	BAXTER HLTHCARE CORP	10 UNITS/ML	N17007 008		MAY	CAHN
>A>	@		100 UNITS/ML	N17007 009		MAY	CAHN
>D>	@	WYETH AYERST	10 UNITS/ML	N17007 008		MAY	CAHN
>D>	@		100 UNITS/ML	N17007 009		MAY	CAHN

HEPARIN SODIUM

>A>	@	BAXTER HLTHCARE CORP	1,000 UNITS/ML	N17007 001		MAY	CAHN
>A>	@		2,500 UNITS/ML	N17007 007		MAY	CAHN
>A>	@		5,000 UNITS/ML	N17007 002		MAY	CAHN
>A>	@		5,000 UNITS/0.5ML	N17007 010		MAY	CAHN
>A>	@		7,500 UNITS/ML	N17007 003		MAY	CAHN
>A>	@		10,000 UNITS/ML	N17007 004		MAY	CAHN
>A>	@		15,000 UNITS/ML	N17007 005		MAY	CAHN
>A>	@		20,000 UNITS/ML	N17007 006		MAY	CAHN
>D>	@	WYETH AYERST	1,000 UNITS/ML	N17007 001		MAY	CAHN
>D>	@		2,500 UNITS/ML	N17007 007		MAY	CAHN
>D>	@		5,000 UNITS/ML	N17007 002		MAY	CAHN
>D>	@		5,000 UNITS/0.5ML	N17007 010		MAY	CAHN
>D>	@		7,500 UNITS/ML	N17007 003		MAY	CAHN
>D>	@		10,000 UNITS/ML	N17007 004		MAY	CAHN
>D>	@		15,000 UNITS/ML	N17007 005		MAY	CAHN
>D>	@		20,000 UNITS/ML	N17007 006		MAY	CAHN

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE

SYRUP; ORAL

HYDROCODONE BITARTRATE AND HOMATROPINE METHYLBROMIDE

>A>	AA	AXIOM PHARM	1.5MG/5ML;5MG/5ML	N40285 001	JUL 19, 1999	MAY	CAHN
>D>	AA	HALSEY	1.5MG/5ML;5MG/5ML	N40285 001	JUL 19, 1999	MAY	CAHN

HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

INDERIDE-40/25

AB WYETH PHARMS INC 25MG;40MG

N18031 001

MAR CAHN

INDERIDE-80/25

AB + WYETH PHARMS INC 25MG;80MG

N18031 002

MAR CAHN

HYDROCODONE BITARTRATE; IBUPROFEN

TABLET; ORAL

HYDROCODONE BITARTRATE AND IBUPROFEN

AB TEVA 7.5MG;200MG

N76023 001 APR 11, 2003 APR NEWA

VICOPROFEN

AB + ABBOTT 7.5MG;200MG

N20716 001 SEP 23, 1997 APR CFTG

HYDROCORTISONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

HYDROCORTONE

@ MERCK EQ 50MG BASE/ML

N12052 001

APR DISC

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OTIC

NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE

AT ALCON 1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML

N62423 001 AUG 25, 1983 FEB CMFD

SUSPENSION/DROPS; OPHTHALMIC

AT ALCON UNIVERSAL 1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML

N62874 001 MAY 11, 1988 FEB CMFD

SUSPENSION/DROPS; OTIC

AT ALCON UNIVERSAL 1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML

N62488 001 NOV 06, 1985 FEB CMFD

HYDROMORPHONE HYDROCHLORIDE

INJECTABLE; INJECTION

HYDROMORPHONE HCL

AP FAULDING 10MG/ML

N76444 001 APR 25, 2003 APR NEWA

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL

ATARAX

@ PFIZER 10MG

N10392 001

FEB DISC

@ 25MG

N10392 004

FEB DISC

@ 50MG

N10392 006

FEB DISC

@ 100MG

N10392 005

FEB DISC

HYDROXYZINE HCL

AB + SIDMAK LABS NJ 10MG

N88617 001 JAN 10, 1986 FEB CRLD

AB + 25MG

N88618 001 JAN 10, 1986 FEB CRLD

AB + 50MG

N88619 001 JAN 10, 1986 FEB CRLD

@ 100MG

N81054 001 SEP 25, 1995 FEB DISC

>A> IBANDRONATE SODIUM

>A> TABLET; ORAL

>A> BONIVA

>A> + ROCHE EQ 2.5MG BASE

N21455 001 MAY 16, 2003 MAY NEWA

IMATINIB MESYLATE

TABLET; ORAL

GLEEVEC

NOVARTIS	100MG	N21588 001	APR 18, 2003	APR	NEWA
+	400MG	N21588 002	APR 18, 2003	APR	NEWA

IPRATROPIUM BROMIDE

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
AB NOVEX	0.021MG/SPRAY	N76156 001	APR 18, 2003	APR	NEWA
AB	0.042MG/SPRAY	N76155 001	APR 18, 2003	APR	NEWA

ISONIAZID

TABLET; ORAL

ISONIAZID

>A> @ AXIOM PHARM	100MG	N80136 001		MAY	CAHN
>A> AA	300MG	N83633 001		MAY	CAHN
>D> @ HALSEY	100MG	N80136 001		MAY	CAHN
>D> AA	300MG	N83633 001		MAY	CAHN

ISOSORBIDE DINITRATE

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

ISOTRETINOIN

CAPSULE; ORAL

CLARAVIS

AB BARR	10MG	N76356 001	APR 11, 2003	APR	NEWA
AB	20MG	N76135 002	APR 11, 2003	APR	NEWA
AB	40MG	N76135 001	APR 11, 2003	APR	NEWA

ISRADIPINE

CAPSULE; ORAL

DYNACIRC

>D> NOVARTIS	2.5MG	N19546 001	DEC 20, 1990	MAY	CAHN
>D> +	5MG	N19546 002	DEC 20, 1990	MAY	CAHN

>A>	RELIANT PHARMS	2.5MG	N19546 001	DEC 20, 1990	MAY	CAHN
>A>	+	5MG	N19546 002	DEC 20, 1990	MAY	CAHN
	TABLET, EXTENDED RELEASE; ORAL					
	DYNACIRC CR					
>D>	+	NOVARTIS	5MG	N20336 001	JUN 01, 1994	MAY CAHN
>D>	+		10MG	N20336 002	JUN 01, 1994	MAY CAHN
>A>	+	RELIANT PHARMS	5MG	N20336 001	JUN 01, 1994	MAY CAHN
>A>	+		10MG	N20336 002	JUN 01, 1994	MAY CAHN

KETOPROFEN

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

KETOROLAC TROMETHAMINE

SOLUTION/DROPS; OPHTHALMIC

>A>	ACULAR LS					
>A>	+	ALLERGAN	0.4%	N21528 001	MAY 30, 2003	MAY NEWA

LACTULOSE

SOLUTION; ORAL

LACTULOSE

AA	VISTAPHARM	10GM/15ML	N74138 001	SEP 30, 1992	MAR	CAHN
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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
		NORPLANT SYSTEM IN PLASTIC CONTAINER				
	+	WYETH PHARMS INC	36MG/IMPLANT	N20088 001	DEC 10, 1990	MAR CAHN

LEVORPHANOL TARTRATE

TABLET; ORAL

LEVO-DROMORAN

@ ICN

2MG

N08720 001	DEC 19, 1991	FEB	DISC
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WHAJ YAK 0001 000 31

LEVORPHANOL TARTRATE

TABLET; ORAL

LEVORPHANOL TARTRATE

+ ROXANE 2MG

N74278 001 MAR 31, 2000 FEB CRLD

LEVOTHYROXINE SODIUM

TABLET; ORAL

LEVO-T

BX ALARA PHARM 0.025MG
 BX 0.05MG
 BX 0.075MG
 BX 0.088MG
 BX 0.1MG
 BX 0.112MG
 BX 0.125MG
 BX 0.15MG
 BX 0.175MG
 BX 0.2MG
 BX + 0.3MG

N21342 001 MAR 01, 2002 APR CAHN
 N21342 002 MAR 01, 2002 APR CAHN
 N21342 003 MAR 01, 2002 APR CAHN
 N21342 004 MAR 01, 2002 APR CAHN
 N21342 005 MAR 01, 2002 APR CAHN
 N21342 006 MAR 01, 2002 APR CAHN
 N21342 007 MAR 01, 2002 APR CAHN
 N21342 008 MAR 01, 2002 APR CAHN
 N21342 009 MAR 01, 2002 APR CAHN
 N21342 010 MAR 01, 2002 APR CAHN
 N21342 011 MAR 01, 2002 APR CAHN

LIDOCAINE HYDROCHLORIDE

JELLY; TOPICAL

LIDOCAINE HCL

AT AKORN 2%

N40433 001 FEB 12, 2003 FEB NEWA

LISINAPRIL

TABLET; ORAL

LISINAPRIL

AB RANBAXY 30MG

N75944 006 FEB 11, 2003 FEB NEWA

ZESTRIL

AB ASTRAZENECA 30MG

N19777 006 JAN 20, 1999 APR CRLD

LITHIUM CARBONATE

CAPSULE; ORAL

LITHIUM CARBONATE

AB ROXANE 150MG

N17812 002 JAN 28, 1987 FEB CTEC

AB WEST WARD 150MG

N76243 002 FEB 24, 2003 FEB NEWA

TABLET, EXTENDED RELEASE; ORAL

AB ABLE 300MG

N76382 001 APR 21, 2003 APR NEWA

>D> LORATADINE

>D> SYRUP; ORAL

>D> CLARITIN

>D> + SCHERING 1MG/ML

N20641 001 OCT 10, 1996 MAY DISC

>A> @ 1MG/ML

N20641 001 OCT 10, 1996 MAY DISC

>D> TABLET; ORAL

>D> + SCHERING 10MG

N19658 001 APR 12, 1993 MAY DISC

>A> @ 10MG

N19658 001 APR 12, 1993 MAY DISC

>D> TABLET, ORALLY DISINTEGRATING; ORAL

>D> CLARITIN REDITABS

>D> + SCHERING 10MG

N20704 001 DEC 23, 1996 MAY DISC

>A>	@	10MG	N20704 001	DEC 23, 1996	MAY	DISC
<u>LORAZEPAM</u>						
CONCENTRATE; ORAL						
LORAZEPAM INTENSOL						
>D>	ROXANE	2MG/ML	N72755 001	JUN 28, 1991	MAY	CRLD
>A>	+	2MG/ML	N72755 001	JUN 28, 1991	MAY	CRLD
INJECTABLE; INJECTION						
ATIVAN						
AP	+	BAXTER HLTHCARE CORP	2MG/ML	N18140 001	FEB	CAHN
AP	+		4MG/ML	N18140 002	FEB	CAHN
<u>MECAMYLAMINE HYDROCHLORIDE</u>						
TABLET; ORAL						
INVERSINE						
	+	TARGACEPT	2.5MG	N10251 001	APR	CAHN
<u>MECLOFENAMATE SODIUM</u>						
CAPSULE; ORAL						
MECLOFENAMATE SODIUM						
>D>	AB	MYLAN	EQ 100MG BASE	N71081 001	SEP 03, 1986	MAY CRLD
>A>	AB	+	EQ 100MG BASE	N71081 001	SEP 03, 1986	MAY CRLD
>D>	MECLOMEN					
>D>	AB	PARKE DAVIS	EQ 50MG BASE	N18006 001	MAY	DISC
>A>	@		EQ 50MG BASE	N18006 001	MAY	DISC
>D>	AB	+	EQ 100MG BASE	N18006 002	MAY	DISC
>A>	@		EQ 100MG BASE	N18006 002	MAY	DISC
<u>MEFLOQUINE HYDROCHLORIDE</u>						
TABLET; ORAL						
MEFLOQUINE HCL						
AB		GENEVA PHARMS	250MG	N76175 001	FEB 20, 2002	APR CAHN
<u>MEGESTROL ACETATE</u>						
SUSPENSION; ORAL						
MEGESTROL ACETATE						
>A>	AB	COPLEY PHARM	40MG/ML	N75681 001	MAY 05, 2003	MAY NEWA
<u>MENOTROPINS (FSH;LH)</u>						
INJECTABLE; INJECTION						
REPRONEX						
>D>	BX	FERRING	75 IU/VIAL;75 IU/VIAL	N21047 001	AUG 27, 1999	MAY CRLD
>A>	BX	+	75 IU/VIAL;75 IU/VIAL	N21047 001	AUG 27, 1999	MAY CRLD
>D>		+	150 IU/VIAL;150 IU/VIAL	N21047 002	AUG 27, 1999	MAY DISC
>A>	@		150 IU/VIAL;150 IU/VIAL	N21047 002	AUG 27, 1999	MAY DISC
<u>MEPERIDINE HYDROCHLORIDE</u>						
INJECTABLE; INJECTION						
MEPERIDINE HCL						
>A>	AP	BAXTER HLTHCARE CORP	25MG/ML	N80455 007	MAY	CAHN
>A>	AP		50MG/ML	N80455 008	MAY	CAHN
>A>	AP		75MG/ML	N80455 009	MAY	CAHN
>A>	AP		100MG/ML	N80455 010	MAY	CAHN

>D>	AP	WYETH AYERST	25MG/ML	N80455 007	MAY	CAHN
>D>	AP		50MG/ML	N80455 008	MAY	CAHN
>D>	AP		75MG/ML	N80455 009	MAY	CAHN
>D>	AP		100MG/ML	N80455 010	MAY	CAHN
		TABLET; ORAL				
>A>	AA	AXIOM PHARM	50MG	N80448 001	MAY	CAHN
>A>	AA		100MG	N80448 002	MAY	CAHN
>D>	AA	HALSEY	50MG	N80448 001	MAY	CAHN
>D>	AA		100MG	N80448 002	MAY	CAHN

MEPERIDINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

MEPERGAN

>A>	@	BAXTER HLTHCARE CORP	25MG/ML;25MG/ML	N11730 001	MAY	CAHN
>D>	@	WYETH AYERST	25MG/ML;25MG/ML	N11730 001	MAY	CAHN

MEPHENTERMINE SULFATE

INJECTABLE; INJECTION

WYAMINE SULFATE

@ BAXTER HLTHCARE CORP

EQ 15MG BASE/ML

N08248 002

FEB CAHN

@

EQ 30MG BASE/ML

N08248 001

FEB CAHN

MEPROBAMATE

TABLET; ORAL

MILTOWN

AA +	MEDPOINTE	600MG	N83919 001	APR	CAHN
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METFORMIN HYDROCHLORIDE

TABLET; ORAL

METFORMIN HCL

AB	PUREPAC PHARM	1GM	N76033 003	JAN 24, 2002	FEB CMS1
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TABLET, EXTENDED RELEASE; ORAL

GLUCOPHAGE XR

+	BRISTOL MYERS SQUIBB	750MG	N21202 004	APR 11, 2003	APR NEWA
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METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE

TABLET; ORAL

AVANDAMET

SB PHARMCO

500MG;EQ 1MG BASE

N21410 001 OCT 10, 2002 APR CAHN

500MG;EQ 2MG BASE

N21410 002 OCT 10, 2002 APR CAHN

+ 500MG;EQ 4MG BASE

N21410 003 OCT 10, 2002 APR CAHN

METHADONE HYDROCHLORIDE

INJECTABLE; INJECTION

DOLOPHINE HCL

+ AAIPHARMA 10MG/ML

N21624 001

APR CAHN

+ ROXANE 10MG/ML

N21624 001

FEB CMS1

METHOCARBAMOL

TABLET; ORAL

METHOCARBAMOL

AA	ABLE	500MG	N40413 001	MAR 17, 2003	MAR NEWA
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AA		750MG	N40413 002	MAR 17, 2003	MAR NEWA
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AA	LANNETT	500MG	N84756 002	MAR 31, 2003	MAR	NEWA
AA	VINTAGE PHARMS	500MG	N40489 001	JAN 29, 2003	JAN	NEWA
AA		750MG	N40489 002	JAN 29, 2003	JAN	NEWA

METHOTREXATE SODIUM

INJECTABLE; INJECTION

METHOTREXATE LPF

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

METHSCOPOLAMINE BROMIDE

TABLET; ORAL

PAMINE FORTE

+	BRADLEY PHARMS	5MG	N08848 002	MAR 25, 2003	MAR	NEWA
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METHYLDOPA

TABLET; ORAL

ALDOMET

>D>	AB	MERCK	125MG	N13400 003		MAY	DISC
>A>		@	125MG	N13400 003		MAY	DISC
>D>	AB		250MG	N13400 001		MAY	DISC
>A>		@	250MG	N13400 001		MAY	DISC

METHYLPHENIDATE HYDROCHLORIDE

TABLET, CHEWABLE; ORAL

METHYLIN

MALLINCKRODT 2.5MG

5MG

+ 10MG

N21475 001	APR 15, 2003	APR	NEWA
N21475 002	APR 15, 2003	APR	NEWA
N21475 003	APR 15, 2003	APR	NEWA

TABLET, EXTENDED RELEASE; ORAL

CONCERTA

>D>	+	ALZA	18MG	N21121 001	AUG 01, 2000	MAY	CAHN
>D>	+		27MG	N21121 004	APR 01, 2002	MAY	CAHN
>D>	+		36MG	N21121 002	AUG 01, 2000	MAY	CAHN
>D>	+		54MG	N21121 003	DEC 08, 2000	MAY	CAHN
>A>	+	MCNEIL CONS SPECLT	18MG	N21121 001	AUG 01, 2000	MAY	CAHN
>A>	+		27MG	N21121 004	APR 01, 2002	MAY	CAHN
>A>	+		36MG	N21121 002	AUG 01, 2000	MAY	CAHN
>A>	+		54MG	N21121 003	DEC 08, 2000	MAY	CAHN

METOCLOPRAMIDE HYDROCHLORIDE

SOLUTION; ORAL

METOCLOPRAMIDE

AA	VISTAPHARM	EQ 5MG BASE/5ML	N75051 001	JAN 26, 2001	APR	CAHN
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MILRINONE LACTATE

INJECTABLE; INJECTION

PRIMACOR IN DEXTROSE 5% IN PLASTIC CONTAINER

>D>	AP	SANOFI SYNTHELABO	EQ 20MG BASE/100ML	N20343 003	AUG 09, 1994	MAY	CRLD
>A>	AP +		EQ 20MG BASE/100ML	N20343 003	AUG 09, 1994	MAY	CRLD

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

TABLET; ORAL

MINOCYCLINE HCL

PAR PHARM

EQ 50MG BASE	N65131 001	APR 16, 2003	APR	NEWA
EQ 75MG BASE	N65131 002	APR 16, 2003	APR	NEWA
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

MOEXIPRIL HYDROCHLORIDE

TABLET; ORAL

MOEXIPRIL HCL

>A>	AB	TEVA	7.5MG	N76204 001	MAY 08, 2003	MAY	NEWA
>A>	AB		15MG	N76204 002	MAY 08, 2003	MAY	NEWA

UNIVASC

>D>		SCHWARZ PHARMA	7.5MG	N20312 001	APR 19, 1995	MAY	CFTG
>A>	AB		7.5MG	N20312 001	APR 19, 1995	MAY	CFTG
>D>	+		15MG	N20312 002	APR 19, 1995	MAY	CFTG
>A>	AB +		15MG	N20312 002	APR 19, 1995	MAY	CFTG

MOXIFLOXACIN HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

VIGAMOX

+	ALCON	0.5%	N21598 001	APR 15, 2003	APR	NEWA
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MUPIROCIN

OINTMENT; TOPICAL

MUPIROCIN

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

SUSPENSION; ORAL

+ ROCHE PALO 200MG/ML

N50759 001 OCT 01, 1998 FEB CAHN

TABLET; ORAL

+ ROCHE PALO 500MG

N50723 001 JUN 19, 1997 FEB CAHN

MYCOPHENOLATE MOFETIL HYDROCHLORIDE

INJECTABLE; INJECTION

+ ROCHE PALO 500MG/VIAL

N50758 001 AUG 12, 1998 FEB CAHN

NABUMETONE

TABLET; ORAL

NABUMETONE

AB IVAX PHARMS 500MG

N76009 001 JAN 24, 2003 JAN NEWA

AB 750MG

N76009 002 JAN 24, 2003 JAN NEWA

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION

NALBUPHINE HCL

>D> AP KING PHARMS 10MG/ML

N74471 001 MAR 19, 1998 MAY DISC

>A> @ 10MG/ML

N74471 001 MAR 19, 1998 MAY DISC

>D> AP 20MG/ML

N74471 002 MAR 19, 1998 MAY DISC

>A> @ 20MG/ML

N74471 002 MAR 19, 1998 MAY DISC

NANDROLONE DECANOATE

INJECTABLE; INJECTION

DECA-DURABOLIN

>D> AO + ORGANON 50MG/ML

N13132 001 JUN 12, 1986 MAY DISC

>D> AO + 100MG/ML

N13132 002 JUN 12, 1986 MAY DISC

>D> AO + 200MG/ML

N13132 003 JUN 12, 1986 MAY DISC

>A> @ ORGANON USA INC 50MG/ML

N13132 001 JUN 12, 1986 MAY DISC

>A> @ 100MG/ML

N13132 002 JUN 12, 1986 MAY DISC

>A> @ 200MG/ML

N13132 003 JUN 12, 1986 MAY DISC

NANDROLONE DECANOATE

>D> AO STERIS 50MG/ML

N86385 001 JAN 13, 1984 MAY CRLD

>A> + 50MG/ML

N86385 001 JAN 13, 1984 MAY CRLD

>D> AO 100MG/ML

N86598 001 JAN 13, 1984 MAY CRLD

>A> + 100MG/ML

N86598 001 JAN 13, 1984 MAY CRLD

>D> AO 200MG/ML

N88128 001 DEC 05, 1983 MAY CRLD

>A> + 200MG/ML

N88128 001 DEC 05, 1983 MAY CRLD

NAPROXEN SODIUM

TABLET, EXTENDED RELEASE; ORAL

NAPRELAN

AB + ELAN PHARM EQ 375MG BASE

N20353 001 JAN 05, 1996 APR CFTG

AB + EQ 500MG BASE

N20353 002 JAN 05, 1996 MAR CFTG

NAPROXEN SODIUM

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

+ AGOURON

EQ 625MG BASE

N21503 001 APR 30, 2003 APR NEWA

NITROFURANTOIN

TABLET; ORAL

FURADANTIN

@ PROCTER AND GAMBLE

50MG

N08693 001

APR DISC

@

100MG

N08693 002

APR DISC

NITROFURANTOIN

@ WATSON LAB

50MG

N80447 001

APR DISC

@ WHITEWORTH TOWN PLSN

100MG

N84085 002

APR DISC

NITROFURAZONE

OINTMENT; TOPICAL

FURACIN

@ SHIRE PHARM

0.2%

N05795 001

MAR DISC

NITROGLYCERIN

FILM, EXTENDED RELEASE; TRANSDERMAL*

NITROGLYCERIN

AB2 MYLAN TECHNOLOGIES

0.1MG/HR

N75033 001 FEB 06, 1998 APR CAHN

AB2

0.2MG/HR

N74609 001 AUG 30, 1996 APR CAHN

AB2

0.4MG/HR

N74607 001 AUG 30, 1996 APR CAHN

AB2

0.6MG/HR

N74559 001 AUG 30, 1996 APR CAHN

INJECTABLE; INJECTION

>D>

TRIDIL

>D>

+ FAULDING

0.5MG/ML

N18537 002 JUN 16, 1983 MAY DISC

>A>

@

0.5MG/ML

N18537 002 JUN 16, 1983 MAY DISC

>D>

AP +

5MG/ML

N18537 001 MAY DISC

>A>

@

5MG/ML

N18537 001 MAY DISC

OINTMENT; TRANSDERMAL

NITROGLYCERIN

+ 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

NOREPINEPHRINE BITARTRATE

AP GENSLA SICOR PHARMS

EQ 1MG BASE/ML

N40455 001 MAR 03, 2003 MAR NEWA

* SEE SECTION 1.3 NITROGLYCERIN, FILM, EXTENDED RELEASE; TRANSDERMAL

NORETHINDRONE ACETATE

TABLET; ORAL

AYGESTIN

AB + WYETH PHARMS INC 5MG

N18405 001 APR 21, 1982 MAR CAHN

NORFLOXACIN

>D> SOLUTION/DROPS; OPHTHALMIC

>D> CHIBROXIN

>D> + MERCK 0.3%

N19757 001 JUN 17, 1991 MAY DISC

>A> @ 0.3%

N19757 001 JUN 17, 1991 MAY DISC

NORGESTREL

TABLET; ORAL

OVRETTE

+ WYETH PHARMS INC 0.075MG

N17031 001 MAR CAHN

OLANZAPINE

TABLET; ORAL

ZYPREXA

>D> LILLY 5MG

N20592 002 SEP 30, 1996 MAY CRLD

>A> + 5MG

N20592 002 SEP 30, 1996 MAY CRLD

>D> + 20MG

N20592 006 SEP 09, 1997 MAY CRLD

>A> 20MG

N20592 006 SEP 09, 1997 MAY CRLD

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

>A> AB MYLAN 10MG

N75876 001 MAY 29, 2003 MAY NEWA

>A> AB 20MG

N75876 002 MAY 29, 2003 MAY NEWA

ORPHENADRINE CITRATE

INJECTABLE; INJECTION

ORPHENADRINE CITRATE

AP BEDFORD LABS 30MG/ML

N40463 001 MAR 04, 2003 MAR NEWA

OXYBUTYNIN

FILM, EXTENDED RELEASE; TRANSDERMAL

OXYTROL

+ WATSON LABS (UTAH) 3.9MG/24HR

N21351 002 FEB 26, 2003 FEB NEWA

OXYBUTYNIN CHLORIDE

TABLET, EXTENDED RELEASE; ORAL

DITROPAN XL

>D> + ALZA 5MG

N20897 001 DEC 16, 1998 MAY CRLD

>A> 5MG

N20897 001 DEC 16, 1998 MAY CRLD

>D> + 10MG

N20897 002 DEC 16, 1998 MAY CRLD

>A> 10MG

N20897 002 DEC 16, 1998 MAY CRLD

OXYTOCIN

INJECTABLE; INJECTION

OXYTOCIN

>A>	@	BAXTER HLTHCARE CORP	10USP UNITS/ML	N18243 001		MAY	CAHN
>D>	@	WYETH AYERST	10USP UNITS/ML	N18243 001		MAY	CAHN

PANCURONIUM BROMIDE

INJECTABLE; INJECTION

PANCURONIUM BROMIDE

>D>	AP	GENSIA SICOR PHARMS	1MG/ML	N72759 001	JUL 31, 1990	MAY	CRLD
>A>	AP	+	1MG/ML	N72759 001	JUL 31, 1990	MAY	CRLD
>D>	AP		2MG/ML	N72760 001	JUL 31, 1990	MAY	CRLD
>A>	AP	+	2MG/ML	N72760 001	JUL 31, 1990	MAY	CRLD
PAVULON							
>D>	AP	+	ORGANON	1MG/ML	N17015 002		MAY DISC
>A>		@		1MG/ML	N17015 002		MAY DISC
>D>	AP	+		2MG/ML	N17015 001		MAY DISC
>A>		@		2MG/ML	N17015 001		MAY DISC

PANTOPRAZOLE SODIUM

INJECTABLE; IV (INFUSION)

PROTONIX IV

+ WYETH PHARMS INC EQ 40MG BASE/VIAL

N20988 001 MAR 22, 2001 MAR CAHN

TABLET, DELAYED RELEASE; ORAL

PROTONIX

+	WYETH PHARMS INC	EQ 20MG BASE
		EQ 20MG BASE
+		EQ 40MG BASE

N20987 002	JUN 12, 2001	MAR	CAHN
N20987 002	JUN 12, 2001	APR	CRLD
N20987 001	FEB 02, 2000	MAR	CAHN

PAROMOMYCIN SULFATE

CAPSULE; ORAL

HUMATIN

>A>	AA	+	KING PHARMS	EQ 250MG BASE	N62310 001		MAY	CAHN
>D>	AA	+	PARKEDALE	EQ 250MG BASE	N62310 001		MAY	CAHN

PEGVISOMANT

INJECTABLE; SUBCUTANEOUS

SOMAVERT

+	PHARMACIA AND UPJOHN	10MG/VIAL
+		15MG/VIAL
+		20MG/VIAL

N21106 001	MAR 25, 2003	MAR	NEWA
N21106 002	MAR 25, 2003	MAR	NEWA
N21106 003	MAR 25, 2003	MAR	NEWA

PERMETHRIN

CREAM; TOPICAL

PERMETHRIN

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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PERPHENAZINE

TABLET; ORAL

TRILAFON

@ SCHERING 2MG
 @ 4MG
 @ 8MG
 @ 16MG

N10775 001 FEB DISC
 N10775 002 FEB DISC
 N10775 003 FEB DISC
 N10775 004 FEB DISC

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

PHENTERMINE HCL

AA ABLE 15MG
 >A> AA AMBI PHARMS 30MG
 AA AMIDE PHARM 15MG
 AA 30MG
 >D> AA KING PHARMS 30MG

N40497 001 MAR 13, 2003 MAR NEWA
 N40083 001 MAR 07, 1997 MAY CAHN
 N40460 001 JAN 14, 2003 JAN NEWA
 N40448 001 JAN 22, 2003 JAN NEWA
 N40083 001 MAR 07, 1997 MAY CAHN

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PHENERGAN VC

@ WYETH AYERST 5MG/5ML;6.25MG/5ML

PROMETH VC PLAIN

AA + ALPHARMA 5MG/5ML;6.25MG/5ML

N08604 003 APR 02, 1984 APR DISC
 N88761 001 NOV 08, 1984 APR CRLD

PHENYTOIN

SUSPENSION; ORAL

PHENYTOIN

AB VISTAPHARM 125MG/5ML

N40342 001 JAN 31, 2001 MAR CAHN

PHENYTOIN SODIUM

INJECTABLE; INJECTION

DILANTIN

@ PARKE DAVIS 50MG/ML

PHENYTOIN

+ ELKINS SINN 50MG/ML

PHENYTOIN SODIUM

@ ABBOTT 50MG/ML

@ 50MG/ML

N10151 001 MAR DISC

N84307 001 MAR CRLD

N89521 001 MAR 17, 1987 MAR DISC

N89744 001 DEC 18, 1987 MAR DISC

PHENYTOIN SODIUM, EXTENDED

CAPSULE; ORAL

DILANTIN

PARKE DAVIS 30MG

N84349 001 FEB CRLD

PILOCARPINE HYDROCHLORIDE

TABLET; ORAL

SALAGEN

MGI PHARMA INC 5MG

+ 7.5MG

N20237 001 MAR 22, 1994 APR CRLD

N20237 002 APR 18, 2003 APR NEWA

PIPERACILLIN SODIUM

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

PIPERACILLIN SODIUM; TAZOBACTAM SODIUM

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

PIRBUTEROL ACETATE

AEROSOL, METERED; INHALATION

MAXAIR

>D>	+	3M	EQ 0.2MG BASE/INH	N19009 001	DEC 30, 1986	MAY	DISC
>A>	@		EQ 0.2MG BASE/INH	N19009 001	DEC 30, 1986	MAY	DISC

PRALIDOXIME CHLORIDE

INJECTABLE; INJECTION

PRALIDOXIME CHLORIDE

@ BAXTER HLTHCARE CORP 300MG/ML

N18799 001 DEC 13, 1982 MAR CAHN

PREDNICARBATE

CREAM; TOPICAL

DERMATOP E EMOLLIENT

+	DERMIK LABS	0.1%	N20279 001	OCT 29, 1993	APR	CTNA
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PREDNISOLONE

SYRUP; ORAL

PREDNISOLONE

>A>	AA	AXIOM PHARM	15MG/5ML	N40287 001	MAY 28, 1999	MAY	CAHN
>D>	AA	HALSEY	15MG/5ML	N40287 001	MAY 28, 1999	MAY	CAHN
	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
		PRELONE					
>D>	AA	+	MURO	N89081 001	FEB 04, 1986	MAY	CAHN
>A>	AA	+	TEVA	N89081 001	FEB 04, 1986	MAY	CAHN

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION; ORAL

PREDNISOLONE SODIUM PHOSPHATE

AA	HI TECH PHARMA	EQ 5MG BASE/5ML	N75183 001	MAR 26, 2003	MAR	NEWA
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PREDNISOLONE SODIUM PHOSPHATE; SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC

SULFACETAMIDE SODIUM AND PREDNISOLONE SODIUM PHOSPHATE

AT	ALCON	EQ 0.23% PHOSPHATE;10%	N73630 001	MAY 27, 1993	APR	CAHN
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PREDNISONE

TABLET; ORAL

PREDNISONE

AB	VINTAGE PHARMS	20MG	N40392 001	FEB 12, 2003	FEB	NEWA
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PROCHLORPERAZINE EDISYLATE

INJECTABLE; INJECTION

PROCHLORPERAZINE EDISYLATE

>A>	AP	GENSIA SICOR PHARMS	EQ 5MG BASE/ML	N40505 001	MAY 30, 2003	MAY	NEWA
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PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

PHENERGAN

Q WYETH AYERST

50MG/ML

N08857 003		APR	DISC
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PROMETHAZINE HCL

AP +	GENSIA SICOR PHARMS	25MG/ML	N40454 001	AUG 22, 2002	APR	CRLD
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AP +		50MG/ML	N40454 002	AUG 22, 2002	APR	CRLD
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AP	PHARMAFORCE	25MG/ML	N40515 001	MAR 19, 2003	MAR	NEWA
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SUPPOSITORY; RECTAL

PHENERGAN

AB +	WYETH AYERST	50MG	N11689 001		FEB	CTEC
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AB	WYETH PHARMS INC	12.5MG	N10926 002		MAR	CAHN
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AB +		25MG	N10926 001		MAR	CAHN
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AB +		50MG	N11689 001		MAR	CAHN
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PROMETHAZINE HCL

AB	ABLE	12.5MG	N40504 001	APR 11, 2003	APR	NEWA
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AB		25MG	N40504 002	APR 11, 2003	APR	NEWA
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AB		50MG	N40449 001	FEB 27, 2003	FEB	NEWA
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AB	G AND W LABS	12.5MG	N40428 002	MAR 31, 2003	MAR	NEWA
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TABLET; ORAL

PHENERGAN

WYETH PHARMS INC

12.5MG

N07935 002		MAR	CAHN
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BP		25MG	N07935 003		MAR	CAHN
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BP +		50MG	N07935 004		MAR	CAHN
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PROPIOMAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

LARGON

>A>	Q BAXTER HLTHCARE CORP	20MG/ML	N12382 002		MAY	CAHN
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>D>	Q WYETH AYERST	20MG/ML	N12382 002		MAY	CAHN
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PROPRANOLOL HYDROCHLORIDE

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

INDERAL

>A>	AP + BAXTER HLTHCARE CORP	1MG/ML	N16419 001		MAY	CAHN
>D>	AP + WYETH AYERST	1MG/ML	N16419 001		MAY	CAHN
	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

PYRIDOSTIGMINE BROMIDE

INJECTABLE; INJECTION

REGONOL

>D>	AP + ORGANON	5MG/ML	N17398 001		MAY	DISC
>A>	@	5MG/ML	N17398 001		MAY	DISC

TABLET; ORAL

PYRIDOSTIGMINE BROMIDE

AB	IMPAX LABS	60MG	N40502 001	APR 24, 2003	APR	NEWA
@	US ARMY	30MG	N20414 001	FEB 05, 2003	FEB	NEWA

QUETIAPINE FUMARATE

TABLET; ORAL

SEROQUEL

+	ASTRAZENECA	EQ 25MG BASE	N20639 001	SEP 26, 1997	MAR	CRLD
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QUINAPRIL HYDROCHLORIDE

TABLET; ORAL

ACCUPRIL

>D>	PFIZER PHARMS	EQ 5MG BASE	N19885 001	NOV 19, 1991	MAY	CFTG
>A>	AB	EQ 5MG BASE	N19885 001	NOV 19, 1991	MAY	CFTG
>D>		EQ 10MG BASE	N19885 002	NOV 19, 1991	MAY	CFTG
>A>	AB	EQ 10MG BASE	N19885 002	NOV 19, 1991	MAY	CFTG
>D>		EQ 20MG BASE	N19885 003	NOV 19, 1991	MAY	CFTG
>A>	AB	EQ 20MG BASE	N19885 003	NOV 19, 1991	MAY	CFTG
>D>	+	EQ 40MG BASE	N19885 004	NOV 19, 1991	MAY	CFTG
>A>	AB +	EQ 40MG BASE	N19885 004	NOV 19, 1991	MAY	CFTG

QUINAPRIL HYDROCHLORIDE

TABLET; ORAL

>A> QUINAPRIL HCL

>A>	AB	TEVA	EQ 5MG BASE
>A>	AB		EQ 10MG BASE
>A>	AB		EQ 20MG BASE
>A>	AB		EQ 40MG BASE

N75504	001	MAY 30, 2003	MAY	NEWA
N75504	002	MAY 30, 2003	MAY	NEWA
N75504	003	MAY 30, 2003	MAY	NEWA
N75504	004	NOV 20, 1998	MAY	NEWA

QUINIDINE GLUCONATE

TABLET, EXTENDED RELEASE; ORAL

QUINAGLUTE

a BERLEX LABS 324MG

QUINIDINE GLUCONATE

>D>	BX	+	MUTUAL PHARM	324MG
>A>		+		324MG
	BX	+		324MG
>D>	BX		WATSON LABS	324MG
>A>		a		324MG
		+		324MG
	BX			324MG

N16647 001 MAR DISC

N89338	001	FEB 11, 1987	MAY	CTEC
N89338	001	FEB 11, 1987	MAY	CTEC
N89338	001	FEB 11, 1987	APR	CRLD
N87810	001	SEP 29, 1982	MAY	DISC
N87810	001	SEP 29, 1982	MAY	DISC
N87810	001	SEP 29, 1982	MAR	CRLD
N87810	001	SEP 29, 1982	APR	CRLD

QUINIDINE SULFATE

TABLET, EXTENDED RELEASE; ORAL

QUINIDEX

AB + WYETH PHARMS INC 300MG

N12796 002 MAR CAHN

>D> RESERPINE; TRICHLORMETHIAZIDE

>D> TABLET; ORAL

>D> METATENSIN #2

>D> AVENTIS PHARMS 0.1MG;2MG

>A> a 0.1MG;2MG

>D> METATENSIN #4

>D> + AVENTIS PHARMS 0.1MG;4MG

>A> a 0.1MG;4MG

N12972	001		MAY	DISC
N12972	001		MAY	DISC

N12972	002		MAY	DISC
N12972	002		MAY	DISC

RILUZOLE

TABLET; ORAL

RILUTEK

AB + AVENTIS 50MG

RILUZOLE

AB IMPAX LABS 50MG

N20599 001 DEC 12, 1995 JAN CFTG

N76173 001 JAN 29, 2003 JAN NEWA

RIMANTADINE HYDROCHLORIDE

TABLET; ORAL

RIMANTADINE HCL

AB AMIDE PHARM 100MG

N76375 001 JAN 14, 2003 JAN NEWA

RISPERIDONE

TABLET, ORALLY DISINTEGRATING; ORAL

RISPERDAL

JOHNSON AND JOHNSON 0.5MG

N21444 001 APR 02, 2003 APR NEWA

	+	1MG	N21444 002	APR 02, 2003	APR	NEWA
		2MG	N21444 003	APR 02, 2003	APR	NEWA
<u>ROSIGLITAZONE MALEATE</u>						
TABLET; ORAL						
AVANDIA						
	SB PHARMCO	EQ 2MG BASE	N21071 002	MAY 25, 1999	APR	CAHN
		EQ 4MG BASE	N21071 003	MAY 25, 1999	APR	CAHN
	+	EQ 8MG BASE	N21071 004	MAY 25, 1999	APR	CAHN
<u>SACROSIDASE</u>						
SOLUTION; ORAL						
SUCRAID						
>D>	+	ORPHAN MEDCL	8,500 IU/ML	N20772 001	APR 09, 1998	MAY CAHN
>A>	+	QOL MEDCL	8,500 IU/ML	N20772 001	APR 09, 1998	MAY CAHN
<u>SEVELAMER HYDROCHLORIDE</u>						
CAPSULE; ORAL						
RENAGEL						
	+	GENZYME	403MG	N20926 001	OCT 30, 1998	APR CAHN
TABLET; ORAL						
		GENZYME	400MG	N21179 001	JUL 12, 2000	APR CAHN
	+		800MG	N21179 002	JUL 12, 2000	APR CAHN
<u>SIROLIMUS</u>						
SOLUTION; ORAL						
RAPAMUNE						
	+	WYETH PHARMS INC	1MG/ML	N21083 001	SEP 15, 1999	MAR CAHN
TABLET; ORAL						
		WYETH PHARMS INC	1MG	N21110 001	AUG 25, 2000	MAR CRLD
	+		2MG	N21110 002	AUG 22, 2002	MAR NEWA
<u>SODIUM IODIDE, I-131</u>						
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
<u>SOMATROPIN RECOMBINANT</u>						
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
<u>SOTALOL HYDROCHLORIDE</u>						
TABLET; ORAL						
>D>		BETAPACE AF				
>D>		BERLEX LABS	40MG	N21151 006	APR 02, 2003	MAY DISC

>A>	@	40MG	N21151 006	APR 02, 2003	MAY	DISC
		40MG	N21151 006	APR 02, 2003	APR	NEWA
>D>		60MG	N21151 007	APR 02, 2003	MAY	DISC
>A>	@	60MG	N21151 007	APR 02, 2003	MAY	DISC
		60MG	N21151 007	APR 02, 2003	APR	NEWA
>D>		100MG	N21151 005	MAR 14, 2003	MAY	DISC
>A>	@	100MG	N21151 005	MAR 14, 2003	MAY	DISC
		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

SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION

SEPTRA

>D> AP + MONARCH PHARMS 80MG/ML;16MG/ML

N18452 001 MAY DISC

>A> @ 80MG/ML;16MG/ML

N18452 001 MAY DISC

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 EQ 20MG BASE

N76398 002 MAR 31, 2003 MAR NEWA

AB ANDRX PHARMS EQ 10MG BASE

N76179 001 FEB 20, 2003 FEB NEWA

AB EQ 20MG BASE

N76179 002 FEB 20, 2003 FEB NEWA

AB BARR EQ 10MG BASE

N70929 001 FEB 20, 2003 FEB NEWA

AB EQ 20MG BASE

N70929 002 FEB 20, 2003 FEB NEWA

AB IVAX PHARMS EQ 10MG BASE

N75740 001 FEB 20, 2003 FEB NEWA

AB EQ 20MG BASE

N75740 002 FEB 20, 2003 FEB NEWA

AB MYLAN EQ 10MG BASE

N74732 002 FEB 20, 2003 FEB NEWA

AB EQ 20MG BASE

N74732 001 FEB 20, 2003 FEB NEWA

AB PHARMACHEMIE EQ 10MG BASE

N74539 001 MAR 31, 2003 APR CAHN

AB EQ 20MG BASE

N74858 001 FEB 20, 2003 FEB NEWA

AB ROXANE EQ 10MG BASE

N76027 001 FEB 20, 2003 FEB NEWA

AB EQ 20MG BASE

N76027 002 FEB 20, 2003 FEB NEWA

AB TEVA EQ 10MG BASE

N74504 001 APR 28, 2003 APR NEWA

AB EQ 10MG BASE

N74539 001 MAR 31, 2003 MAR NEWA

AB EQ 10MG BASE

N75797 001 FEB 20, 2003 FEB NEWA

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

>D> TECHNETIUM TC-99M PYRO/TRIMETA PHOSPHATES KIT

>D> INJECTABLE; INJECTION

>D> PYROLITE

>D> CIS N/A

>A> @ N/A

N17684 001

MAY DISC

N17684 001

MAY DISC

TESTOSTERONE

GEL; TOPICAL

ANDROGEL

BX + UNIMED PHARMS 1%

N21015 001 FEB 28, 2000 APR CTEC

TESTIM

BX + AUXILIUM A2 1%

N21454 001 OCT 31, 2002 APR CTEC

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL

TETRACYCLINE HCL

>A> AB AXIOM PHARM 250MG

N60736 001

MAY CAHN

>A> AB 500MG

N60736 002

MAY CAHN

>D> AB HALSEY 250MG

N60736 001

MAY CAHN

>D> AB 500MG

N60736 002

MAY CAHN

THALIDOMIDE

CAPSULE; ORAL

THALOMID

CELGENE

100MG

N20785 002 JAN 17, 2003 JAN NEWA

+

200MG

N20785 003 JAN 17, 2003 JAN NEWA

THIOTHIXENE

CAPSULE; ORAL

NAVANE

AB PFIZER 1MG

N16584 001

FEB CAHN

AB 2MG

N16584 002

FEB CAHN

AB + 5MG

N16584 003

FEB CAHN

AB 10MG

N16584 004

FEB CAHN

20MG

N16584 005

FEB CAHN

THIOTHIXENE HYDROCHLORIDE

CONCENTRATE; ORAL

AA + PFIZER EQ 5MG BASE/ML

N16758 001

FEB CAHN

INJECTABLE; INJECTION

@ PFIZER

EQ 2MG BASE/ML

N16904 001

FEB CAHN

+

EQ 10MG BASE/VIAL

N16904 002

FEB CAHN

TIZANIDINE HYDROCHLORIDE

TABLET; ORAL

TIZANIDINE HCL

AB BARR EQ 2MG BASE

N76371 001 APR 09, 2003 APR NEWA

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

TORSEMIDE

TABLET; ORAL

TORSEMIDE

>A>	AB	PAR PHARM	5MG
>A>	AB		10MG
>A>	AB		20MG
>A>	AB		100MG
>A>	AB	PLIVA PHARM IND	5MG
>A>	AB		10MG
>A>	AB		20MG

N76226	001	MAY 27, 2003	MAY	NEWA
N76226	002	MAY 27, 2003	MAY	NEWA
N76226	003	MAY 27, 2003	MAY	NEWA
N76226	004	MAY 27, 2003	MAY	NEWA
N76346	001	MAY 30, 2003	MAY	NEWA
N76346	002	MAY 30, 2003	MAY	NEWA
N76346	003	MAY 30, 2003	MAY	NEWA

TRAMADOL HYDROCHLORIDE

TABLET; ORAL

TRAMADOL HCL

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

LOTION; TOPICAL

TRIAMCINOLONE ACETONIDE

AT	ALTANA	0.025%
AT		0.1%

N40467	001	APR 21, 2003	APR	NEWA
N40467	002	APR 21, 2003	APR	NEWA

TRICHLORMETHIAZIDE

TABLET; ORAL

METAHYDRIN

>D>	BP	AVENTIS PHARMS	2MG
>A>	@		2MG
>D>	BP		4MG
>A>	@		4MG

N12594	001	JUN 16, 1988	MAY	DISC
N12594	001	JUN 16, 1988	MAY	DISC
N12594	002	JUN 16, 1988	MAY	DISC
N12594	002	JUN 16, 1988	MAY	DISC

TRIMETHOPRIM

TABLET; ORAL

PROLOPRIM

>D>	AB	+ MONARCH PHARMS	200MG
>A>	@		200MG

TRIMETHOPRIM

>D>	AB	TEVA	200MG
>A>	+		200MG

N17943	003	JUL 14, 1982	MAY	DISC
N17943	003	JUL 14, 1982	MAY	DISC

N71259	001	JUN 18, 1987	MAY	CRLD
N71259	001	JUN 18, 1987	MAY	CRLD

UREA, C-13

FOR SOLUTION; ORAL

HELICOSOL

>D>	+	METABOLIC SOLUTIONS	125MG/VIAL
>A>	@		125MG/VIAL

PYLORI-CHEK BREATH TEST

@ DEVICES 100MG/VIAL

N21092	001	DEC 17, 1999	MAY	DISC
N21092	001	DEC 17, 1999	MAY	DISC
N20900	001	FEB 04, 1999	MAR	CAHN

VECURNIUM BROMIDE

INJECTABLE; INJECTION

NORCURON

>D>	AP	+ ORGANON	10MG/VIAL
>A>	@		10MG/VIAL

N18776	002	APR 30, 1984	MAY	DISC
N18776	002	APR 30, 1984	MAY	DISC

VECURONIUM BROMIDE

INJECTABLE; INJECTION

VECURONIUM BROMIDE

>D>	AP	BEDFORD	10MG/VIAL	N75549 001	JUN 13, 2000	MAY	CRLD
>A>	AP	+	10MG/VIAL	N75549 001	JUN 13, 2000	MAY	CRLD

VENLAFAXINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

EFFEXOR XR

WYETH PHARMS INC

EQ 37.5MG BASE

N20699 001 OCT 20, 1997 MAR CAHN

EQ 75MG BASE

N20699 002 OCT 20, 1997 MAR CRLD

@

EQ 100MG BASE

N20699 003 OCT 20, 1997 MAR CAHN

+

EQ 150MG BASE

N20699 004 OCT 20, 1997 MAR CRLD

TABLET; ORAL

EFFEXOR

@ WYETH PHARMS INC

EQ 12.5MG BASE

N20151 001 DEC 28, 1993 MAR CAHN

EQ 25MG BASE

N20151 002 DEC 28, 1993 MAR CRLD

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

>D> VIDARABINE

>D> OINTMENT; OPHTHALMIC

>D> VIRA-A

>D> + PARKEDALE 3%

N50486 001 MAY DISC

>A> @ 3%

N50486 001 MAY DISC

VINORELBINE TARTRATE

INJECTABLE; INJECTION

NAVELBINE

AP + GLAXOSMITHKLINE EQ 10MG BASE/ML

N20388 001 DEC 23, 1994 FEB CFTG

VINORELBINE TARTRATE

AP GENSLA SICOR PHARMS EQ 10MG BASE/ML

N76028 001 FEB 03, 2003 FEB NEWA

ZOLEDRONIC ACID

INJECTABLE; IV (INFUSION)

ZOMETA

+ NOVARTIS EQ 4MG BASE/5ML

N21223 002 MAR 07, 2003 MAR NEWA

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

EPINEPHRINE

AEROSOL, METERED; INHALATION

BRONKAID MIST

>D>

+ STERLING

0.25MG/INH

N16803 001

MAY DISC

>D>

@

0.25MG/INH

N16803 001

MAY DISC

>A>

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

+ SCHERING

1MG/ML

N20641 002 NOV 27, 2002 APR CRLD

1MG/ML

N20641 002 NOV 27, 2002 MAR NEWA

TABLET; ORAL

+ SCHERING

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

WYETH CONS

10MG

N21375 001 DEC 19, 2002 APR CRLD

CLARITIN REDITABS

+ SCHERING

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

+ SCHERING 5MG;120MG
5MG;120MG

N19670 002 NOV 27, 2002 APR CRLD
N19670 002 NOV 27, 2002 MAR NEWA

CLARITIN-D 24 HOUR

+ SCHERING 10MG;240MG
10MG;240MG

N20470 002 NOV 27, 2002 APR CRLD
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

PERMETHRIN

LOTION; TOPICAL

NIX

+ INSIGHT PHARMS 1%

N19918 001 MAY 02, 1990 MAR CAHN

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

CUMULATIVE SUPPLEMENT NUMBER 5 MAY '03

NO MAY 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
May 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 MA: Suite 1640	DD: 3/31/2003	Prevention of serious adverse events associated with vascular leak syndrome caused by Interleukin-2 therapy	BioMedicines, Inc. 2000 Powell Street Emeryville CA 94608
2',3',5'-tri-o-acetyluridine MA:	DD: 1/13/2003	Treatment of mitochondrial disease	Repligen Corporation 41 Seyon Street Building 1, Suite 100 Waltham MA 02453
4,5-dibromorhodamine 123 Theralux Irradiation Device MA:	DD: 4/10/2003	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 MA:	DD: 1/15/2003	Treatment of multiple myeloma	Celgene Corporation 7 Powder Horn Drive Warren NJ 07059
a-Galactosidase A Corporation Plant-Produced Human a-Glactosidase MA:	DD: 1/21/2003	Treatment of Fabry's disease	Large Scale Biology 3333 Vacaville Parkway Suite 1000 Vacaville CA 95688
alendronate Fosamax MA:	DD: 3/31/2003	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 University Activase University Jefferson 1-109 MA:	DD: 1/27/2003	Treatment of intraventricular hemorrhage associated with intracerebral hemorrhage	Daniel F. Hanley, MD Johns Hopkins Johns Hopkins 600 N. Wolfe St., Baltimore MD 21287

Orphan Products Designations and Approvals List

May 2003

AMG 531	DD: 3/27/2003	Treatment of immune thrombocytopenic purpura.	Amgen, Inc. One Amgen Center
Drive	MA:		Thousand Oaks CA
91320-1799			
anti-CD23 IgG1, kappa monoclonal Inc. antibody	DD: 2/12/2003	Treatment of chronic lymphocytic leukemia	IDEC Pharmaceuticals, 3030 Callan Road San Diego CA 92121
	MA:		
Anti-CEA Sheep-human chimeric monoclonal antibody labeled Court w/iodine-131 (KAb201)	DD: 5/21/2003	Treatment of pancreatic cancer	KS Biomedix Ltd Ground Floor, 1 Occam
	MA:		Surrey Research Park Guilford, Surrey, GU2
7HJ UK			
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	Treatment for renal cell carcinoma	Lorus Therapeutics, Inc 2 Meridan Road Toronto, Ontario M9W427 CANADA
	MA:		
arsenic trioxide	DD: 5/13/2003	Treatment of chronic lymphocytic leukemia	Cell Therapeutics, Inc. 501 Elliott avenue West 501 Elliott avenue West Suite 400 Seattle WA 98119
Trisenox	MA:		
arsenic trioxide Trisenox	DD: 6/13/2003	Treatment of liver cancer	Cell Therapeutics, Inc. 501 Elliott Avenue West Suite 400 Seattle WA 98119
	MA:		
bifidobacterium longum infantis Limited 35624	DD: 1/16/2003	Treatment of pediatric Crohn's disease	Alimentary Health Guardwell, Kinsale County Cork, Ireland
	MA:		
bortezomib Pharmaceuticals, Inc. VELCADE	DD: 1/15/2003	To treat multiple myeloma	Millennium 75 Sidney Street Cambridge MA 02139
	MA:		

Orphan Products Designations and Approvals List

May 2003

Capsaicin	DD: 5/2/2003	Treatment of painful HIV-associated neuropathy	NeurogesX, Inc. San Carlos Business
Park	MA:		981F Industrial Road San Carlos CA 94070-
4117			
cinacalcet	DD: 5/12/2003	Treatment of hypercalcemia in patients with parathyroid carcinoma	Amgen, Inc.
Drive	MA:		One Amgen Center Thousand Oaks CA
91320-1799			
Defibrotide	DD: 5/21/2003	For the treatment of hepatic veno-occlusive disease	Gentium SpA Piazza XX Settembre, 2 22079 Villa Guardia
(CO)	MA:		ITALY
dextran 1	DD: 3/21/2003	Treatment of cystic fibrosis	BCY LifeSciences Inc. 160 Eglinton Ave. East Suite 600 Toronto, Ontario M4P
3B5			
DHA-paclitaxel	DD: 5/1/2003	Treatment of adenocarcinoma of the stomach or lower esophagus	Protarga, Inc. 2200 Renaissance
Boulevard Taxoprexin Boulevard	MA:		2200 Renaissance Suite 450 King of Prussia PA
19406			
diferuloylmethane LLC	DD: 6/13/2003	Treatment of cystic fibrosis	Seer Pharmaceuticals, P. O. Box 138 Southport CT 06890
	MA:		
diphenylcyclophenone	DD: 6/13/2003	Treatment of chronic severe forms of alopecia areata (Alopecia Totalis)	Lloyd E. King, Jr. 1900 Patterson Street Suite 104 Nashville TN 37203
	MA:		
	MA:	[AT]/Alopecia Universalis [AU])	
Factor XIII [A2] homodimer, recombinant DNA origin East	DD: 5/21/2003	Treatment of congenital FXIII deficiency	ZymoGenetics, Inc. 1201 Eastlake Avenue Seattle WA 98102
	MA:		

Orphan Products Designations and Approvals List

May 2003

Human Anti-tumor Necrosis factor alpha monoclonal antibody Parkway	DD: 1/16/2003	Treatment of uveitis of the posterior segment of non-infectious etiology, and	Centocor, Inc. 200 Great Valley
1307	MA:	uveitis of the anterior segment of non-infectious etiology and refractory to conventional therapy	Malvern PA 19355-
infliximab Remicade Parkway	DD: 5/6/2003	Treatment of giant cell arteritis	Centocor, Inc. 200 Great Valley
1307	MA:		Malvern PA 19355-
infliximab Remicade Parkway	DD: 5/21/2003	Treatment of chronic sarcoidosis	Centocor, Inc. 200 Great Valley
1307	MA:		Malvern PA 19355-
INGN 201 Inc. ADVEXIN	DD: 1/27/2003	Treatment of head and neck cancer	Introgen Therapeutics, 2250 Holcombe Blvd Houston TX 77030
	MA:		
	MA:		
iron(III)-hexacyanoferrate(II) Pharmzeutische	DD: 5/1/2003	Treatment of patients with known or suspected internal contamination with	Heyl Chemisch- Fabrik GMBH & Co,
KG		radioactive or non-radioactive cesium or thallium	Goerzallee 253 Goerzallee 253 D-14167 Berlin, Federal
Radiogardase-Cs / Antidotum	MA:		
Republic of	MA:		Germany
Mafosfamide (formerly Oncology)	DD: 1/21/2003	Treatment of neoplastic meningitis	Baxter Oncology GmbH ASTA Medica Daimlerstrasse 40 60314 Frankfurt/Main Germany
	MA:		
MaxAdFVIII Corporation	DD: 3/3/2003	Treatment of Hemophilia A	GenStar Therapeutics 10865 Altman Row Suite 200 San Diego CA 92121-
	MA:		
1113			

Orphan Products Designations and Approvals List

May 2003

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-
Xcytrin	MA:		
4521	MA:		
myristoylated recombinant SCR1-3 of human complement reseptor Pk, type I	DD: 5/21/2003	Prevention of delayed graft function in solid organ transplant	Adprotech, Ltd. Chesterford Research
APT070	MA:		
Saffron Walden,	MA:		Little Chesterford, Essex, CB10 1XK UK
polyinosinic-polycytidilic acid	DD: 3/3/2003	Treatment of flavivirus infections including those due to West Nile,	Ribopharm, Inc. 3203 Cleveland Ave.,
NW	MA:	Japanese encephalitis, dengue, St. Louis	3203 Cleveland Ave.,
Poly-ICLC	MA:	encephalitis, yellow fever, Murray valley, and Banzai viruses	Washington DC 20008-
NW			
3450			
Protaxel	DD: 5/21/2003	Treatment of ovarian cancer	Biophysica, Inc. 3333 North Torrey Pines
Court	MA:		Suite 100 La Jolla CA 92037
recombinant adeno-associated Technologies Corp. virus alpha 1-antitrypsin vector rAAV-AAT	DD: 1/27/2003	Treatment of alpha1-antitrypsin deficiency	Applied Genetic 12085 Research Drive
	MA:		Suite 110
	MA:		Alachua FL 32615
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 mutiple sclerosis patients who are both HLA-DR2 positive and	Virogenomics, Inc. 9020 SW Washington
Square Road	MA:	glycoprotein residues 35-55	Suite 380
	MA:	autoreactive to myelin oligodendrocyte	Tigard, OR 97223-4332
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:		

Orphan Products Designations and Approvals List

May 2003

repository corticotropin or Pharmaceuticals, Inc. adrenocorticotrophic hormone H.P. Acthar Gel	DD: 5/21/2003 MA: MA:	Treatment of infantile spasms	Questcor 3260 Whipple Road Union City CA 94587-
1217			
resiniferatoxin	DD: 5/13/2003 MA: DASS/PPCS/NIDCR/NIH	Treatment of intractable pain at end-stage disease	Andrew J. Mannes, Md Bldg 10/Rm 2N236 - 10 Convent Drive Bethesda MD 20892
Ribavirin USP	DD: 4/4/2003	Treatment of chronic hepatitis C in pediatric patients	Schering Corporation 2000 Galloping Hill 2000 Galloping Hill
Road REBETOL Road	MA:		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
suberoylanilide hydroxamic acid	DD: 6/12/2003	Treatment of multiple myeloma	Aton Pharma, Inc. 777 Old Saw Mill River Tarrytown NY 10591-
Road 6717	MA:		
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**

NO MAY 2003 ADDITIONS

THE UNIVERSITY OF CHICAGO
LIBRARY

1910

1911

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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 EXCLUS CODE EXPIRES
020977 001	ABACAVIR SULFATE; ZIAGEN	5034394	DEC 18, 2011		
020978 001	ABACAVIR SULFATE; ZIAGEN	5034394*PED	JUN 18, 2012		
020213 001	ACETYLCOLINE CHLORIDE; MIOCHOL-E	5034394	DEC 18, 2011		
020899 001	ALBUMIN HUMAN; OPTISON	5034394*PED	JUN 18, 2012		
		6261546	APR 29, 2019	U-506	
		5573751	APR 25, 2012		
		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		
		5849726	JUN 06, 2015	U-303	
		6008207	JUN 06, 2015		
		6090410	DEC 02, 2012		
		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		
		6008207*PED	DEC 06, 2015	U-303	
		6090410*PED	JUN 02, 2013		
		6194004*PED	JUN 02, 2013		
		5358941	DEC 02, 2012		
		4621077	AUG 06, 2007	U-114	
		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		
		6008207*PED	JUN 06, 2015	U-303	
		6090410*PED	JUN 02, 2013		
		5358941	DEC 02, 2012		
		4621077	AUG 06, 2007	U-114	
		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		
		6008207*PED	JUN 06, 2015	U-303	
		6090410*PED	JUN 02, 2013		
		5358941	DEC 02, 2012		
		4621077	AUG 06, 2007	U-114	
		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		
		6008207*PED	JUN 06, 2015	U-303	
		6090410*PED	JUN 02, 2013		
		5358941	DEC 02, 2012		
		4621077	AUG 06, 2007	U-114	
		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		
		6008207*PED	JUN 06, 2015	U-303	
		6090410*PED	JUN 02, 2013		
		5358941	DEC 02, 2012		
		4621077	AUG 06, 2007	U-114	
		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		
		6008207*PED	JUN 06, 2015	U-303	
		6090410*PED	JUN 02, 2013		

[illegible]

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	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 SACCCHARATE				PC	SEP 15, 2003
040422 006	AMPHETAMINE ASPARTATE; DEXTROAMP SACCCHARATE				PC	SEP 15, 2003
040422 007	AMPHETAMINE ASPARTATE; DEXTROAMP SACCCHARATE				PC	SEP 15, 2003
021549 001	APREPITANT; EMEND	5719147	JUN 29, 2012		NCE	MAR 26, 2008
		5538982	JUL 23, 2013			
		6048859	JUN 29, 2012			
		6096742	JUL 01, 2018			
		6235735	JUN 29, 2012			
		5719147	JUN 29, 2012			
		5538982	JUL 23, 2013			
		6048859	JUN 29, 2012			
		6096742	JUL 01, 2018			
021549 002	APREPITANT; EMEND				NCE	MAR 26, 2008
		6235735	JUN 29, 2012			
		4734416	MAR 29, 2005			
		5006528	OCT 20, 2009			
		4734416	MAR 29, 2005			
		5006528	OCT 20, 2009			
		4734416	MAR 29, 2005			
		5006528	OCT 20, 2009			
		4734416	MAR 29, 2005			
		5006528	OCT 20, 2009			
		4734416	MAR 29, 2005			
		5006528	OCT 20, 2009			
		4734416	MAR 29, 2005			
		5006528	OCT 20, 2009			
021411 001	ATOMOXETINE HYDROCHLORIDE; STRATTERA	5658590	JAN 11, 2015		U-494 NCE	NOV 26, 2007
		5658590*PED	JUL 11, 2015		U-494 PED	MAY 26, 2008
021411 002	ATOMOXETINE HYDROCHLORIDE; STRATTERA	5658590	JAN 11, 2015		U-494 NCE	NOV 26, 2007
		5658590*PED	JUL 11, 2015		U-494 PED	MAY 26, 2008
021411 003	ATOMOXETINE HYDROCHLORIDE; STRATTERA	5658590	JAN 11, 2015		U-494 NCE	NOV 26, 2007
		5658590*PED	JUL 11, 2015		U-494 PED	MAY 26, 2008
021411 004	ATOMOXETINE HYDROCHLORIDE; STRATTERA	5658590	JAN 11, 2015		U-494 NCE	NOV 26, 2007
		5658590*PED	JUL 11, 2015		U-494 PED	MAY 26, 2008
021411 005	ATOMOXETINE HYDROCHLORIDE; STRATTERA	5658590	JAN 11, 2015		U-494 NCE	NOV 26, 2007
		5658590*PED	JUL 11, 2015		U-494 PED	MAY 26, 2008
021411 006	ATOMOXETINE HYDROCHLORIDE; STRATTERA	5658590	JAN 11, 2015		U-494 NCE	NOV 26, 2007
		5658590*PED	JUL 11, 2015		U-494 PED	MAY 26, 2008
021470 001	AZELAIC ACID; FINACEA	5780676	NOV 18, 2018		U-509	
021055 001	BEXAROTENE; TARGRETIN	5780676	JUL 14, 2015		U-510	
021056 001	BEXAROTENE; TARGRETIN	5780676	JUL 14, 2015		U-510	

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>						
021602 001	BORTEZOMIB; VELCADE	5780454	OCT 28, 2014		NCE	MAY 13, 2008
>ADD>		6083903	OCT 28, 2014	U-515		
>ADD>		6297217	OCT 28, 2014	U-515		
>ADD>		6562873	JUL 10, 2021			
>ADD>		6562873*PED	JAN 10, 2022			
021262 001	BRIMONIDINE TARTRATE; ALPHAGAN P					
>ADD>						
076260 001	BRIMONIDINE TARTRATE; BRIMONIDINE TARTRATE					
075766 001	CALCITRIOL; CALCITRIOL				PC	SEP 16, 2003
075766 002	CALCITRIOL; CALCITRIOL				PC	SEP 17, 2003
075823 001	CALCITRIOL; CALCITRIOL				PC	SEP 17, 2003
075823 002	CALCITRIOL; CALCITRIOL				PC	SEP 17, 2003
075836 001	CALCITRIOL; CALCITRIOL				PC	SEP 17, 2003
075836 002	CALCITRIOL; CALCITRIOL				PC	SEP 17, 2003
020637 001	CARMUSTINE; GLIADEL	4789724	AUG 01, 2006		I-382	FEB 25, 2006
		4757128	AUG 01, 2006			
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		
		4525358*PED	DEC 25, 2007	U-295		
		6469009	JUL 13, 2019	U-295		
		6469009*PED	JAN 13, 2020	U-295		
		6489329	APR 08, 2016			
		6489329*PED	OCT 08, 2016			
021159 001	CICLOPIROX; LOPROX				NDF	FEB 28, 2006
021473 001	CIPROFLOXACIN; CIPRO XR	4670444	DEC 09, 2003		NDF	DEC 13, 2005
020839 001	CLOPIDOGREL BISULFATE; PLAVIX	6504030	JUN 10, 2019			
019758 001	CLOZAPINE; CLOZARIL				I-380	DEC 18, 2005
019758 002	CLOZAPINE; CLOZARIL				I-380	DEC 18, 2005
021141 001	COLESEVELAM HYDROCHLORIDE; WELCHOL	6066678	JUN 10, 2014	U-323		
021176 001	COLESEVELAM HYDROCHLORIDE; WELCHOL	6066678	JUN 10, 2014	U-323		
017821 001	CYCLOBENZAPRINE HYDROCHLORIDE; FLEXERIL					
021165 001	DESLOMATADINE; CLARINEX					
		4659716	APR 21, 2004	U-427	D-78	FEB 03, 2006
		4863931	SEP 15, 2008	U-427	NCE	DEC 21, 2006
		4804666	FEB 14, 2006	U-428	PED	JUN 21, 2007
		5595997	DEC 30, 2014	U-429		
		6100274	JUL 07, 2019	U-429		
		4659716*PED	OCT 21, 2004	U-427		
		4804666*PED	AUG 14, 2006	U-428		
		4863931*PED	MAR 15, 2009	U-428		
		5595997*PED	JUN 30, 2015	U-429		
		6100274*PED	JAN 07, 2020	U-429		
021312 001	DESLOMATADINE; CLARINEX				NCE	DEC 21, 2006
					PED	JUN 21, 2007

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
021392 001	DILTIAZEM HYDROCHLORIDE;CARDIZEM LA	5288505	JUN 26, 2011		NDF	FEB 06, 2006
021392 002	DILTIAZEM HYDROCHLORIDE;CARDIZEM LA	5529791	JUN 25, 2013			
021392 003	DILTIAZEM HYDROCHLORIDE;CARDIZEM LA	5288505	JUN 26, 2011		NDF	FEB 06, 2006
021392 004	DILTIAZEM HYDROCHLORIDE;CARDIZEM LA	5529791	JUN 25, 2013			
021392 005	DILTIAZEM HYDROCHLORIDE;CARDIZEM LA	5288505	JUN 26, 2011		NDF	FEB 06, 2006
021392 006	DILTIAZEM HYDROCHLORIDE;CARDIZEM LA	5529791	JUN 25, 2013			
020401 006	DILTIAZEM HYDROCHLORIDE;TIAZAC	5288505	JUN 26, 2011		NDF	FEB 06, 2006
021168 001	DIVALPROEX SODIUM;DEPAKOTE ER	5529791	JUN 25, 2013			
021168 002	DIVALPROEX SODIUM;DEPAKOTE ER	6511678	DEC 18, 2018			
020941 001	DOCOSANOL;ABREVA	6511678	DEC 18, 2018			
020972 001	EFAVIRENZ;SUSTIVA	4874794	APR 28, 2014			
020972 002	EFAVIRENZ;SUSTIVA	6555133	APR 06, 2019	U-248		
020972 003	EFAVIRENZ;SUSTIVA	6555133	APR 06, 2019	U-248		
021360 001	EFAVIRENZ;SUSTIVA	6555133	APR 06, 2019	U-248		
021481 001	ENFUVRTIDE;FUZEON	5663169	SEP 02, 2014			
021437 001	EPLERENONE; INSPIRA	5464933	JUN 07, 2013	NCE	MAR 13, 2008	
021437 002	EPLERENONE; INSPIRA	6133418	JUN 07, 2013			
021437 003	EPLERENONE; INSPIRA	6475491	JUN 07, 2015	U-248		
019386 004	ESMOLOL HYDROCHLORIDE;BREVIBLOC	6534093	DEC 08, 2019	U-3		
019386 006	ESMOLOL HYDROCHLORIDE;BREVIBLOC	6534093	DEC 08, 2019	U-3		
019386 005	ESMOLOL HYDROCHLORIDE;BREVIBLOC DOUBLE STR	6534093	DEC 08, 2019	U-3		
021367 001	ESTRADIOL ACETATE;FEMRING	6528540	JAN 12, 2021			
021367 002	ESTRADIOL ACETATE;FEMRING	4593119	JUN 03, 2003			
020527 001	ESTROGENS, CONJUGATED;PREMPRO	6310094	JAN 12, 2021			
020527 003	ESTROGENS, CONJUGATED;PREMPRO	6528540	JAN 12, 2021			
020527 004	ESTROGENS, CONJUGATED;PREMPRO	4593119	JUN 03, 2003			
>ADD>		6310094	JAN 12, 2021			
>ADD>		5855906	DEC 19, 2015	U-508 NP	MAR 20, 2006	
>ADD>		5855906	DEC 19, 2015	U-508 NP	MAR 20, 2006	
>ADD>		RE36247	MAY 02, 2006	D-79	MAR 12, 2006	
>ADD>		5547948	JAN 17, 2015	D-79	MAR 12, 2006	
>ADD>		5210081	FEB 26, 2012	NP	MAR 12, 2006	
>ADD>		5876746	JUN 07, 2015	D-79	MAR 12, 2006	
021180 001	ETHINYL ESTRADIOL;ORTHO EVRA	5972377	JUN 07, 2015	U-514	MAR 12, 2006	
>ADD>				U-514		

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
020747 001	FENTANYL CITRATE; ACTIQ	4863737	SEP 05, 2006			
		5785989	SEP 05, 2006			
020747 002	FENTANYL CITRATE; ACTIQ	4863737	SEP 05, 2006			
		5785989	SEP 05, 2006			
020747 003	FENTANYL CITRATE; ACTIQ	4863737	SEP 05, 2006			
		5785989	SEP 05, 2006			
020747 004	FENTANYL CITRATE; ACTIQ	4863737	SEP 05, 2006			
		5785989	SEP 05, 2006			
020747 005	FENTANYL CITRATE; ACTIQ	4863737	SEP 05, 2006			
		5785989	SEP 05, 2006			
020747 006	FENTANYL CITRATE; ACTIQ	4863737	SEP 05, 2006			
		5785989	SEP 05, 2006			
019813 001	FENTANYL; DURAGESIC	4588580	JUL 23, 2004	U-43 NPP		MAY 20, 2006
		4588580*PED	JAN 23, 2005	U-43 PED		NOV 20, 2006
019813 002	FENTANYL; DURAGESIC	4588580	JUL 23, 2004	U-43 NPP		MAY 20, 2006
		4588580*PED	JAN 23, 2005	U-43 PED		NOV 20, 2006
019813 003	FENTANYL; DURAGESIC	4588580	JUL 23, 2004	U-43 NPP		MAY 20, 2006
		4588580*PED	JAN 23, 2005	U-43 PED		NOV 20, 2006
019813 004	FENTANYL; DURAGESIC	4588580	JUL 23, 2004	U-43 NPP		MAY 20, 2006
		4588580*PED	JAN 23, 2005	U-43 PED		NOV 20, 2006
020625 001	FEXOFENADINE HYDROCHLORIDE; ALLEGRA	5578610	NOV 26, 2013	U-192 M-25		MAY 12, 2006
		5855912	FEB 28, 2015	PED		NOV 12, 2006
		5738872	FEB 28, 2015			
		5932247	FEB 28, 2015			
		6037353	MAR 14, 2017			
		6113942	FEB 28, 2015			
		6187791	MAY 11, 2012			
		6399632	MAY 11, 2012			
		5578610*PED	MAY 26, 2014			
		5738872*PED	AUG 28, 2015			
		5855912*PED	AUG 28, 2015			
		5932247*PED	AUG 28, 2015			
		6037353*PED	SEP 14, 2017			
		6113942*PED	AUG 28, 2015			
		6187791*PED	NOV 11, 2012			
		6399632*PED	NOV 11, 2012			
		5578610	NOV 26, 2013			
		5738872	FEB 28, 2015			
		5855912	FEB 28, 2015			
		5932247	FEB 28, 2015			
		6037353	MAR 14, 2017			
		6113942	FEB 28, 2015			
		6187791	MAY 11, 2012			
		6399632	MAY 11, 2012			
		5578610*PED	MAY 26, 2014			
		5855912*PED	AUG 28, 2015			
		5932247*PED	AUG 28, 2015			
		6037353*PED	SEP 14, 2017			
		6113942*PED	AUG 28, 2015			
		6187791*PED	NOV 11, 2012			
		6399632*PED	NOV 11, 2012			
020872 001	FEXOFENADINE HYDROCHLORIDE; ALLEGRA	5578610	NOV 26, 2013	NDF		FEB 25, 2003
		5738872	FEB 28, 2015	PED		AUG 25, 2003
		5855912	FEB 28, 2015	M-25		MAY 12, 2006
		5932247	FEB 28, 2015	PED		NOV 12, 2006
		6037353	MAR 14, 2017			
		6113942	FEB 28, 2015			
		6187791	MAY 11, 2012			
		6399632	MAY 11, 2012			
		5578610*PED	MAY 26, 2014			
		5855912*PED	AUG 28, 2015			
		5932247*PED	AUG 28, 2015			
		6037353*PED	SEP 14, 2017			
		6113942*PED	AUG 28, 2015			
		6187791*PED	NOV 11, 2012			
		6399632*PED	NOV 11, 2012			

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020872 002	PEXOFENADINE HYDROCHLORIDE; ALLEGRA	5578610	NOV 26, 2013	U-139	NDF	FEB 25, 2003
		5932247	FEB 28, 2015		PED	AUG 25, 2003
		5855912	FEB 28, 2015		M-25	MAY 12, 2006
		6037353	MAR 14, 2017	U-138	PED	NOV 12, 2006
		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		
		5578610	NOV 26, 2013	U-139	NDF	FEB 25, 2003
		5932247	FEB 28, 2015		PED	AUG 25, 2003
5855912	FEB 28, 2015		M-25	MAY 12, 2006		
6037353	MAR 14, 2017	U-138	PED	NOV 12, 2006		
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				
5578610	NOV 26, 2013		M-25	MAY 12, 2006		
5855912	FEB 28, 2015		PED	NOV 12, 2006		
6037353	MAR 14, 2017	U-138				
6039974	JUL 31, 2018					
6113942	FEB 28, 2015					
6187791	MAY 11, 2012	U-138				
6399632	MAY 11, 2012	U-468				
5578610*PED	MAY 26, 2014					
5855912*PED	AUG 28, 2015					
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				
5578610	NOV 26, 2013					
5855912	FEB 28, 2015					
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6113942	FEB 28, 2015					
6187791	MAY 11, 2012	U-138				
6399632	MAY 11, 2012	U-468				
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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				
5578610	NOV 26, 2013					
5855912	FEB 28, 2015					
6037353	MAR 14, 2017	U-138				
6039974	JUL 31, 2018					
6113942	FEB 28, 2015					
6187791	MAY 11, 2012	U-138				
6399632	MAY 11, 2012	U-468				
5578610*PED	MAY 26, 2014					
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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				
5578610	NOV 26, 2013					
5855912	FEB 28, 2015					
6037353	MAR 14, 2017	U-138				
6039974	JUL 31, 2018					
6113942	FEB 28, 2015					
6187791	MAY 11, 2012	U-138				
6399632	MAY 11, 2012	U-468				
5578610*PED	MAY 26, 2014					
5855912*PED	AUG 28, 2015					
5932247*PED	AUG 28, 2015					
6037353*PED	SEP 14, 2017	U-138				
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6187791*PED	NOV 11, 2012	U-138				
6399632*PED	NOV 11, 2012	U-468				
5578610	NOV 26, 2013					
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6037353	MAR 14, 2017	U-138				
6039974	JUL 31, 2018					
6113942	FEB 28, 2015					
6187791	MAY 11, 2012	U-138				
6399632	MAY 11, 2012	U-468				
5578610*PED	MAY 26, 2014					
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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				
5578610	NOV 26, 2013					
5855912	FEB 28, 2015					
6037353	MAR 14, 2017	U-138				
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6187791	MAY 11, 2012	U-138				
6399632	MAY 11, 2012	U-468				
5578610*PED	MAY 26, 2014					
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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				
5578610	NOV 26, 2013					
5855912	FEB 28, 2015					
6037353	MAR 14, 2017	U-138				
6039974	JUL 31, 2018					
6113942	FEB 28, 2015					
6187791	MAY 11, 2012	U-138				
6399632	MAY 11, 2012	U-468				
5578610*PED	MAY 26, 2014					
5855912*PED	AUG 28, 2015					
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				
5578610	NOV 26, 2013					
5855912	FEB 28, 2015					
6037353	MAR 14, 2017	U-138				
6039974	JUL 31, 2018					
6113942	FEB 28, 2015					
6187791	MAY 11, 2012	U-138				
6399632	MAY 11, 2012	U-468				
5578610*PED	MAY 26, 2014					
5855912*PED	AUG 28, 2015					
5932247*PED	AUG 28, 2015					
6037353*PED	SEP 14, 2017	U-138				
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6187791*PED	NOV 11, 2012	U-138				
6399632*PED	NOV 11, 2012	U-468				
5578610	NOV 26, 2013					
5855912	FEB 28, 2015					
6037353	MAR 14, 2017	U-138				
6039974	JUL 31, 2018					
6113942	FEB 28, 2015					
6187791	MAY 11, 2012	U-138				
6399632	MAY 11, 2012	U-468				
5578610*PED	MAY 26, 2014					
5855912*PED	AUG 28, 2015					
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				
5578610	NOV 26, 2013					
5855912	FEB 28, 2015					
6037353	MAR 14, 2017	U-138				
6039974	JUL 31, 2018					
6113942	FEB 28, 2015					
6187791	MAY 11, 2012	U-138				
6399632	MAY 11, 2012	U-468				
5578610*PED	MAY 26, 2014					
5855912*PED	AUG 28, 2015					
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				
5578610	NOV 26, 2013					
5855912	FEB 28, 2015					
6037353	MAR 14, 2017	U-138				
6039974	JUL 31, 2018					
6113942	FEB 28, 2015					
6187791	MAY 11, 2012	U-138				
6399632	MAY 11, 2012	U-468				
5578610*PED	MAY 26, 2014					
5855912*PED	AUG 28, 2015					
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				
5578610	NOV 26, 2013					
5855912	FEB 28, 2015					
6037353	MAR 14, 2017	U-138				
6039974	JUL 31, 2018					
6113942	FEB 28, 2015					
6187791	MAY 11, 2012	U-138				
6399632	MAY 11, 2012	U-468				
5578610*PED	MAY 26, 2014					
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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				
5578610	NOV 26, 2013					
5855912	FEB 28, 2015					
6037353	MAR 14, 2017	U-138				
6039974	JUL 31, 2018					
6113942	FEB 28, 2015					
6187791	MAY 11, 2012	U-138				
6399632	MAY 11, 2012	U-468				
5578610*PED	MAY 26, 2014					
5855912*PED	AUG 28, 2015					
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				
5578610	NOV 26, 2013					
5855912	FEB 28, 2015					
6037353	MAR 14, 2017	U-138				
6039974	JUL 31, 2018					
6113942	FEB 28, 2015					
6187791	MAY 11, 2012	U-138				
6399632	MAY 11, 2012	U-468				
5578610*PED	MAY 26, 2014					
5855912*PED	AUG 28, 2015					
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				
5578610	NOV 26, 2013					
5855912	FEB 28, 2015					
6037353	MAR 14, 2017	U-138				
6039974	JUL 31, 2018					
6113942	FEB 28, 2015					
6187791	MAY 11, 2012	U-138				
6399632	MAY 11, 2012	U-468				
5578610*PED	MAY 26, 2014					
5855912*PED	AUG 28, 2015					
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				
5578610	NOV 26, 2013					
5855912	FEB 28, 2015					
6037353	MAR 14, 2017	U-138				
6039974	JUL 31, 2018					
6113942	FEB 28, 2015					
6187791	MAY 11, 2012	U-138				
6399632	MAY 11, 2012	U-468				
5578610*PED	MAY 26, 2014					
5855912*PED	AUG 28, 2015					
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				
5578610	NOV 26, 2013					
5855912	FEB 28, 2015					
6037353	MAR 14, 2017	U-138				
6039974	JUL 31, 2018					
6113942	FEB 28, 2015					
6187791	MAY 11, 2012	U-138				
6399632	MAY 11, 2012					

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020101 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4335121	NOV 14, 2003		NPP	JAN 03, 2006
		5270305	SEP 07, 2010	U-387	PED	JUL 03, 2006
020974 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4992474	FEB 12, 2008	U-211	NPP	JAN 03, 2006
		5225445	FEB 12, 2008		PED	JUL 03, 2006
020974 002	FLUOXETINE HYDROCHLORIDE; PROZAC	5126375	FEB 12, 2008		NPP	JAN 03, 2006
		5290815	MAR 01, 2011		PED	JUL 03, 2006
021077 001	FLUTICASONE PROPIONATE; ADVAIR DISKUS 100/50	4335121*PED	MAY 14, 2004		NC	AUG 24, 2003
		4335121	NOV 14, 2003		PED	FEB 24, 2004
		5270305	SEP 07, 2010			
021077 002	FLUTICASONE PROPIONATE; ADVAIR DISKUS 250/50	4992474	FEB 12, 2008			
		5225445	FEB 12, 2008			
		5126375	FEB 12, 2008			
		5290815	MAR 01, 2011			
		4335121*PED	MAY 14, 2004			
		4335121	NOV 14, 2003		NC	AUG 24, 2003
		5270305	SEP 07, 2010		PED	FEB 24, 2004
021077 003	FLUTICASONE PROPIONATE; ADVAIR DISKUS 500/50	4992474	FEB 12, 2008			
		5225445	FEB 12, 2008			
		5126375	FEB 12, 2008			
		5290815	MAR 01, 2011			
		4335121*PED	MAY 14, 2004			
		4335121	NOV 14, 2003		NC	AUG 24, 2003
		5270305	SEP 07, 2010		PED	FEB 24, 2004
019957 001	FLUTICASONE PROPIONATE; CUTIVATE	4335121	NOV 14, 2003			
		4335121*PED	MAY 14, 2004			
019958 001	FLUTICASONE PROPIONATE; CUTIVATE	4335121	NOV 14, 2003			
		4335121*PED	MAY 14, 2004			
020121 001	FLUTICASONE PROPIONATE; FLONASE	4335121	NOV 14, 2003			
		4335121*PED	MAY 14, 2004			
					D-76	MAY 23, 2005
					PED	NOV 23, 2005
					M-24	MAY 01, 2006
					PED	DEC 01, 2006
020548 001	FLUTICASONE PROPIONATE; FLOVENT	4335121	NOV 14, 2003			
		4335121*PED	MAY 14, 2004			
020548 002	FLUTICASONE PROPIONATE; FLOVENT	4335121	NOV 14, 2003			
		4335121*PED	MAY 14, 2004			
020548 003	FLUTICASONE PROPIONATE; FLOVENT	4335121	NOV 14, 2003			
		4335121*PED	MAY 14, 2004			
020549 001	FLUTICASONE PROPIONATE; FLOVENT	4335121	NOV 14, 2003			
		4335121*PED	MAY 14, 2004			
020549 002	FLUTICASONE PROPIONATE; FLOVENT	4335121	NOV 14, 2003			
		4335121*PED	MAY 14, 2004			
					U-409	
					U-409	
					U-409	

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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
020549 003	FLUTICASONE PROPIONATE; FLOVENT	4335121	NOV 14, 2003	U-409		
020833 001	FLUTICASONE PROPIONATE; FLOVENT DISKUS 50	4335121*PED	MAY 14, 2004	U-409		
020833 002	FLUTICASONE PROPIONATE; FLOVENT DISKUS 100	4335121	NOV 14, 2003	U-409		
020833 003	FLUTICASONE PROPIONATE; FLOVENT DISKUS 250	4335121*PED	MAY 14, 2004	U-409		
020261 001	FLUVASTATIN SODIUM; LESCOL	4335121	NOV 14, 2003	U-409		
020261 002	FLUVASTATIN SODIUM; LESCOL	4335121*PED	MAY 14, 2004	U-409		
021192 001	FLUVASTATIN SODIUM; LESCOL XL	5354772	OCT 11, 2011	U-109		
020831 001	FORMOTEROL FUMARATE; FORADIL	5354772	OCT 11, 2011	U-109		
019915 002	FOSINOPRIL SODIUM; MONOPRIL	5354772	OCT 11, 2011	U-413		
019915 003	FOSINOPRIL SODIUM; MONOPRIL	5354772	OCT 11, 2011	U-413		
019915 004	FOSINOPRIL SODIUM; MONOPRIL	5354772	OCT 11, 2011	U-413		
020286 001	FOSINOPRIL SODIUM; MONOPRIL-HCT	5354772	OCT 11, 2011	U-109		
020286 002	FOSINOPRIL SODIUM; MONOPRIL-HCT	5354772	OCT 11, 2011	U-109		
021493 001	GATIFLOXACIN; ZYMAR	6488027	MAR 08, 2019			
021399 001	GEFITINIB; IRESSA	4337201	DEC 04, 2002			
021158 001	GEMIFLOXACIN MESYLATE; FACTIVE	5006344	JUL 10, 2009			
020329 001	GLIPIZIDE; GLUCOTROL XL	5006344*PED	JAN 10, 2010			
		4337201	DEC 04, 2002			
		5006344	JUL 10, 2009			
		4337201*PED	JAN 10, 2010			
		5006344	JUL 10, 2009			
		4337201	DEC 04, 2002			
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		4337201*PED	JAN 10, 2010			
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		4337201	DEC 04, 2002			

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
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	U-111		
		5545413	JUL 21, 2008	U-111		
		5591454	JAN 07, 2014	U-111		
		6372252	APR 28, 2020	U-489		
021282 002	GUAFENESIN; MUCINEX	5616599	APR 01, 2014	U-500		
>ADD>	HYDROCHLOROTHIAZIDE; BENICAR HCT	5616599	APR 01, 2014	U-500		
>ADD>	HYDROCHLOROTHIAZIDE; BENICAR HCT	5616599	APR 01, 2014	U-500		
>ADD>	HYDROCHLOROTHIAZIDE; BENICAR HCT	5616599	APR 01, 2014	U-500		
021455 001	IBANDRONATE SODIUM; BONIVA					
021321 001	ICODextrin; EXTRANEAL	6248726	JUN 19, 2018	U-495	NCE	MAY 16, 2008
		4761237	AUG 02, 2005	U-495		
		4886789	DEC 12, 2006	U-495		
		6077836	JUN 20, 2017	U-495		
021335 001	IMATINIB MESYLATE; GLEEVEC				I-392	MAY 20, 2006
>ADD>	IMATINIB MESYLATE; GLEEVEC				I-392	MAY 20, 2006
>ADD>	IMATINIB MESYLATE; GLEEVEC				NCE	MAY 10, 2006
021588 001	IMATINIB MESYLATE; GLEEVEC	5521184	MAY 28, 2013		I-376	DEC 20, 2005
					ODE	FEB 01, 2009
					ODE	MAY 10, 2008
					I-391	MAY 20, 2006
					NCE	MAY 10, 2006
021588 002	IMATINIB MESYLATE; GLEEVEC	5521184	MAY 28, 2013		I-376	DEC 20, 2005
					ODE	FEB 01, 2009
					ODE	MAY 10, 2008
					I-391	MAY 20, 2006
					D-80	MAY 01, 2006
021081 001	INSULIN GLARGINE; LANTUS	4364921	MAR 06, 2005	U-498		
021425 001	IOPROMIDE; ULTRAVIST (PHARMACY	4364921	MAR 06, 2005	U-498		
021425 002	IOPROMIDE; ULTRAVIST (PHARMACY	5047407*PED	MAY 17, 2010			
020857 001	LAMIVUDINE; COMBIVIR	5047407	NOV 17, 2009			
		5047407	NOV 17, 2009			
021003 001	LAMIVUDINE; EPIVIR-HBV	5047407	NOV 17, 2009			
		5047407*PED	MAY 17, 2010			
021004 001	LAMIVUDINE; EPIVIR-HBV	5047407	NOV 17, 2009			
		5047407*PED	MAY 17, 2010			
020241 001	LAMOTRIGINE; LAMICTAL				I-387	JAN 17, 2006
020241 002	LAMOTRIGINE; LAMICTAL				I-387	JAN 17, 2006
020241 003	LAMOTRIGINE; LAMICTAL				I-387	JAN 17, 2006
020241 004	LAMOTRIGINE; LAMICTAL				I-387	JAN 17, 2006
020241 005	LAMOTRIGINE; LAMICTAL				I-387	JAN 17, 2006
020241 006	LAMOTRIGINE; LAMICTAL				I-387	JAN 17, 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 CODE	EXCLUS CODE	EXCLUS EXPIRES
020764 001	LAMOTRIGINE; LAMICTAL CD				I-387	JAN 17, 2006
020764 002	LAMOTRIGINE; LAMICTAL CD				I-387	JAN 17, 2006
020764 003	LAMOTRIGINE; LAMICTAL CD				I-387	JAN 17, 2006
020764 004	LAMOTRIGINE; LAMICTAL CD				I-387	JAN 17, 2006
021488 001	LEUPROLIDE ACETATE; ELIGARD				NP	FEB 13, 2006
020837 001	LEVABUTEROL HYDROCHLORIDE; XOPENEX	5362755	NOV 08, 2011	U-332		
020634 001	LEVOFLOXACIN; LEVAQUIN				I-393	MAY 23, 2006
020634 002	LEVOFLOXACIN; LEVAQUIN				I-393	MAY 23, 2006
020634 003	LEVOFLOXACIN; LEVAQUIN				I-393	MAY 23, 2006
020635 001	LEVOFLOXACIN; LEVAQUIN				I-393	MAY 23, 2006
020635 002	LEVOFLOXACIN; LEVAQUIN IN DEXTROSE				I-393	MAY 23, 2006
020635 003	LEVOFLOXACIN; LEVAQUIN IN DEXTROSE				I-393	MAY 23, 2006
021199 001	LEVOFLOXACIN; QUIXIN				I-393	MAY 23, 2006
021301 001	LEVOTHYROXINE SODIUM; LEVOXYL	5503407	DEC 20, 2010			
021301 002	LEVOTHYROXINE SODIUM; LEVOXYL	6555581	FEB 15, 2022			
021301 003	LEVOTHYROXINE SODIUM; LEVOXYL	6555581	FEB 15, 2022			
021301 004	LEVOTHYROXINE SODIUM; LEVOXYL	6555581	FEB 15, 2022			
021301 005	LEVOTHYROXINE SODIUM; LEVOXYL	6555581	FEB 15, 2022			
021301 006	LEVOTHYROXINE SODIUM; LEVOXYL	6555581	FEB 15, 2022			
021301 007	LEVOTHYROXINE SODIUM; LEVOXYL	6555581	FEB 15, 2022			
021301 008	LEVOTHYROXINE SODIUM; LEVOXYL	6555581	FEB 15, 2022			
021301 009	LEVOTHYROXINE SODIUM; LEVOXYL	6555581	FEB 15, 2022			
021301 010	LEVOTHYROXINE SODIUM; LEVOXYL	6555581	FEB 15, 2022			
021301 011	LEVOTHYROXINE SODIUM; LEVOXYL	6555581	FEB 15, 2022			
021301 012	LEVOTHYROXINE SODIUM; LEVOXYL	6555581	FEB 15, 2022			
020612 001	LIDOCAINE; LIDODERM	5589180	MAR 17, 2009	U-485		
		5411738	MAY 02, 2012			
		5827529	OCT 27, 2015	U-486		
		5709869	MAR 17, 2009	U-485		
		5601838	MAY 02, 2012	U-488		
021130 001	LINEZOLID; ZYVOX				NPP	DEC 19, 2005
021130 002	LINEZOLID; ZYVOX				NPP	DEC 19, 2005
021131 001	LINEZOLID; ZYVOX				NPP	DEC 19, 2005
021132 001	LINEZOLID; ZYVOX				NPP	DEC 19, 2005
021226 001	LOPINAVIR; KALETRA					
019658 002	LORATADINE; CLARITIN					
		6521651	NOV 01, 2017			
		4659716	APR 21, 2004	U-142		
		4659716*PED	OCT 21, 2004	U-142		
		4863931	SEP 15, 2008			
		4863931*PED	MAR 15, 2009			
		4659716	APR 21, 2004	U-142		
		4659716*PED	OCT 21, 2004	U-142		
		4863931	SEP 15, 2008			
		4863931*PED	MAR 15, 2009			
020641 002	LORATADINE; CLARITIN					
		6132758	JUN 01, 2018			

[illegible]

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
020845 003 019921 001	NITRIC OXIDE; INOMAX OFLOXACIN; OCUFLOX	5873359 4382892 4551456 4382892* 4551456* 5616599 5616599 5616599 4695578 4753789 6030643	JAN 23, 2013 SEP 02, 2003 NOV 14, 2003 MAR 02, 2004 MAY 14, 2004 APR 01, 2014 APR 01, 2014 APR 01, 2014 JAN 25, 2005 JUN 24, 2006 MAY 16, 2017	U-297 ODE U-80 U-80 U-500 U-500 U-500 U-44 U-497		MAY 22, 2003 NOV 22, 2003
021286 002 021286 001 021286 003 020007 003	OLMESARTAN MEDOXOMIL; BENEVAS OLMESARTAN MEDOXOMIL; BENICAR OLMESARTAN MEDOXOMIL; BENICAR ONDANSETRON HYDROCHLORIDE; ZOFRAN PRESERVATIVE					
020776 001 017577 001	OXAPROZIN POTASSIUM; DAYPRO ALTA OXYBUTYNNIN CHLORIDE; DITROPAN					
018211 001	OXYBUTYNNIN CHLORIDE; DITROPAN					
020897 001	OXYBUTYNNIN CHLORIDE; DITROPAN XL					
020897 002	OXYBUTYNNIN CHLORIDE; DITROPAN XL					
020897 003	OXYBUTYNNIN CHLORIDE; DITROPAN XL					
021351 002 020936 001	OXYBUTYNNIN; OXYTROL PAROXETINE HYDROCHLORIDE; PAXIL CR					
020936 002	PAROXETINE HYDROCHLORIDE; PAXIL CR					
020936 003	PAROXETINE HYDROCHLORIDE; PAXIL CR					
021106 001	PEGVISOMANT; SOMAVERT	6548084 6548084* 6548084* 6548084* 6057292 5849535 5958879 5350836 5681809 6057292 5849535 5958879 5350836 5681809 6057292 5849535 5958879 5350836 5681809 6469015	JUL 19, 2016 JAN 19, 2017 JUL 19, 2016 JAN 19, 2017 JUL 19, 2016 JAN 19, 2017 SEP 21, 2015 SEP 21, 2015 SEP 27, 2011 SEP 27, 2011 SEP 27, 2011 SEP 27, 2011 SEP 27, 2011 SEP 27, 2011 SEP 27, 2011 SEP 27, 2011 SEP 27, 2011 SEP 27, 2011 SEP 27, 2011 SEP 27, 2011 OCT 22, 2019	U-507 NCE U-507 U-507 U-507 U-507 NCE U-507 U-507 U-507 U-507 U-507 U-507 NCE U-507 U-507 U-507 U-507 U-507 U-507 U-507 U-507 U-501		MAR 25, 2008
021106 002	PEGVISOMANT; SOMAVERT					
021106 003	PEGVISOMANT; SOMAVERT					
020629 001	PENCICLOVIR SODIUM; DENAVIR					

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
076061 001	PERGOLIDE MESYLATE; PERGOLIDE MESYLATE				PC	MAY 31, 2003
076061 002	PERGOLIDE MESYLATE; PERGOLIDE MESYLATE				PC	MAY 31, 2003
076061 003	PERGOLIDE MESYLATE; PERGOLIDE MESYLATE				PC	MAY 31, 2003
021438 001	PROPRANOLOL HYDROCHLORIDE; INNOPRAN XL				NP	MAR 12, 2006
021438 002	PROPRANOLOL HYDROCHLORIDE; INNOPRAN XL				NP	MAR 12, 2006
>ADD>		6500454	DEC 31, 2022			
>ADD>		6500454	DEC 31, 2022	U-71		
>ADD>		5403856	APR 04, 2012	U-71		
>ADD>		5403856	APR 01, 2012	U-71		
>ADD>		5403856	APR 01, 2012	U-71		
>ADD>		5403856	APR 04, 2012	U-71		
>ADD>		6524570	NOV 01, 2016	U-499		
>ADD>		6524570*PED	MAY 01, 2017	U-499		
020903 001	RIBAVIRIN; REBETOL				M-26	MAR 06, 2005
020903 002	RIBAVIRIN; REBETOL				M-26	MAR 06, 2005
021444 001	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					
019839 001	SERTRALINE HYDROCHLORIDE; ZOLOFT	4562829	MAY 01, 2004	U-503		
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					
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		
>ADD>		5212155	MAY 18, 2010	U-291		
>ADD>		5308847	MAY 03, 2011	U-292		
>ADD>		5403833	APR 04, 2012	U-293		
>ADD>		5989591	MAR 11, 2018			
>ADD>		5288480	JUL 16, 2008			
020231 001	SODIUM FLUORIDE; COLGATE TOTAL					
020280 007	SOMATROPIN RECOMBINANT; GENOTROPIN				ODE	OCT 31, 2004
020280 001	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
020280 002	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT				ODE	OCT 31, 2004

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
021454 001	TESTOSTERONE; TESTIM	6561977	OCT 23, 2020		NP	OCT 31, 2005
020785 001	THALIDOMIDE; THALOMID	6561976	AUG 28, 2018			
		6045501	AUG 28, 2018	U-371 ODE		JUL 16, 2005
020785 002	THALIDOMIDE; THALOMID	6315720	OCT 23, 2020	U-442		
		6561977	OCT 23, 2020			
		6561976	AUG 28, 2018			
020785 003	THALIDOMIDE; THALOMID	6045501	AUG 28, 2018	U-371 ODE		JUL 16, 2005
		6315720	OCT 23, 2020	U-442		
		6561977	OCT 23, 2020			
		6561976	AUG 28, 2018			
		4513006	SEP 26, 2004			
	TOPIRAMATE; TOPAMAX	4513006	SEP 26, 2004			
020505 001	TOPIRAMATE; TOPAMAX	4513006	SEP 26, 2004			
020505 002	TOPIRAMATE; TOPAMAX	4513006	SEP 26, 2004			
020505 003	TOPIRAMATE; TOPAMAX	4513006	SEP 26, 2004			
020505 004	TOPIRAMATE; TOPAMAX	4513006	SEP 26, 2004			
020505 005	TOPIRAMATE; TOPAMAX	4513006	SEP 26, 2004			
020505 006	TOPIRAMATE; TOPAMAX	4513006	SEP 26, 2004			
020844 001	TOPIRAMATE; TOPAMAX SPRINKLE	4513006	SEP 26, 2004			
020844 002	TOPIRAMATE; TOPAMAX SPRINKLE	4513006	SEP 26, 2004			
020844 003	TOPIRAMATE; TOPAMAX SPRINKLE	4513006	SEP 26, 2004			
021257 001	TRAVOPROST; TRAVATAN					
021108 001	TRETINOIN; RENOVA					
020550 001	VALACYCLOVIR HYDROCHLORIDE; VALTREX	6531141	MAR 07, 2020		M-23	FEB 13, 2006
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-381	SEP 09, 2005
020699 004	VENLAFAXINE HYDROCHLORIDE; EFFEXOR XR				I-389	APR 01, 2006
020552 001	VERAPAMIL HYDROCHLORIDE; COVERA-HS				I-261	FEB 11, 2006
					I-261	FEB 11, 2006
					I-261	FEB 11, 2006
020552 002	VERAPAMIL HYDROCHLORIDE; COVERA-HS				I-261	FEB 11, 2006
		4612008	SEP 16, 2003	U-366		
		6146662	AUG 14, 2007			
		4612008	SEP 16, 2003			
		6146662	AUG 14, 2007	U-366		

PATENT AND EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE PATENT AND EXCLUSIVITY COLUMNS, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 23RD EDITION FOR A FULL LISTING OF PATENT AND EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). THE CUMULATIVE SUPPLEMENT WILL LIST NEW CODES ADDED SINCE THE LAST ANNUAL EDITION.

EXCLUSIVITY DOSING SCHEDULE

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

EXCLUSIVITY INDICATION

- I-380 TO TREAT PATIENTS WITH SCHIZOPHRENIA OR SCHIZOAFFECTIVE DISORDER AT RISK FOR EMERGENT SUICIDAL BEHAVIOR
- I-381 TREATMENT OF COLD SORES (HERPES LABIALIS) IN ADULT AND ADOLESCENT PATIENTS 12 YEARS OF AGE AND OLDER
- I-382 FOR NEWLY-DIAGNOSED HIGH GRADE MALIGNANT GLIOMA PATIENTS AS AN ADJUNCT TO SURGERY AND RADIATION
- I-383 TREATMENT OF TYPE 2 DIABETIC NEPHROPATHY
- 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>=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 THAN 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.....
- I-391 TX OF PED PTS W/PH+ CHRONIC PHASE CML WHOSE DISEASE RECUR AFTER STEM CELL TRANSPLANT OR WHO ARE RESIST TO INTERFERON ALPHA. NO CONTROLLED TRIALS DEMONSTRATE CLIN BENEFIT, SUCH AS IMPROVEMENT IN DISEASE RELATED SX OR INCREASING SURVIVAL
- I-392 TX OF PED PATIENTS W/PH+ CHRONIC PHASE CML DISEASE RECUR AFTER STEM CELL TRNSPLT OR RESIST TO INTERFERON ALPHA THERAPY.NO CONTROLLED TRIALS DEMONSTRATING A CLINICAL BENEFIT SUCH AS IMPROVE IN DISEASE RELATED SX OR INCREASED SURVIVAL
- I-393 CHRONIC BACTERIAL PROSTATITIS

EXCLUSIVITY MISCELLANEOUS

- M-23 INFORMATION REGARDING ELIMINATION ADDED TO CLINICAL PHARMACOLOGY, STUDY RESULTS IN PATIENTS WITH HEPATIC AND RENAL IMPAIRMENT
- M-24 INFORMATION ON RESULTS OF A LONG TERM LONGITUDINAL GROWTH STUDY AND PEDIATRIC SAFETY INFORMATION
- M-25 ADDITIONAL SAFETY & PK INFORMATION IN CHILDREN 6 MONTHS TO LESS THAN 6 YEARS OF AGE ADDED TO PKG INSERT
- M-26 INCORPORATION OF INFORMATION CONTAINED IN THE PEG-INTRON PACKAGE INSERT INTO THE REBETOL PACKAGE INSERT AND MEDGUIDE-PEG-INTRON WAS APPROVED FOR USE IN COMBINATION WITH REBETOL FOR TREATMENT OF CHRONIC HEPATITIS C VIRUS INFECTION ON 8/7/01

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
- U-509 TREATMENT OF CUTANEOUS MANIFESTATIONS OF CUTANEOUS T-CELL LYMPHOMA IN PATIENTS WHO ARE REFRACTORY TO AT LEAST ONE PRIOR SYSTEMIC THERAPY
- U-510 TOPICAL TREATMENT OF CUTANEOUS LESIONS IN PATIENTS WITH CUTANEOUS T-CELL LYMPHOMA (STAGE IA AND IB) WHO HAVE REFRACTORY OR PERSISTENT DISEASE AFTER OTHER THERAPIES OR WHO HAVE NOT TOLERATED OTHER THERAPIES
- U-511 USE OF QUINOLONE COMPOUNDS AGAINST ANAEROBIC PATHOGENIC BACTERIA
- U-512 USE OF QUINOLONE COMPOUNDS AGAINST ATYPICAL UPPER RESPIRATORY PATHOGENIC BACTERIA
- U-513 METHODS OF USE OF ANTIMICROBIAL COMPOUNDS AGAINST PATHOGENIC MYCOPLASMA BACTERIA
- U-514 PREVENTION OF OVULATION IN A WOMAN
- U-515 TREATMENT OF MULTIPLE MYELOMA PATIENTS WHO HAVE RECEIVED AT LEAST TWO PRIOR THERAPIES AND HAVE DEMONSTRATED DISEASE PROGRESSION ON THE LAST THERAPY



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