

APPROVED DRUG PRODUCTS

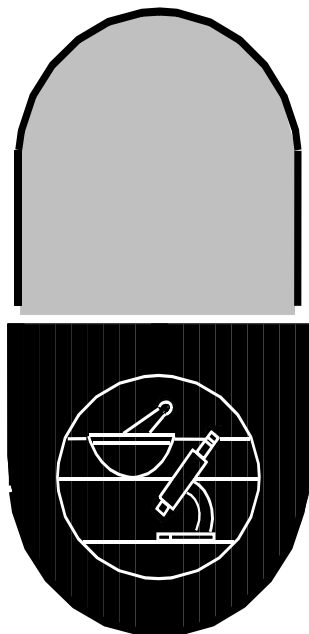
With Therapeutic Equivalence Evaluations



The "Orange Book"

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**CUMULATIVE
SUPPLEMENT 4
APRIL 2005**



**APPROVED
DRUG PRODUCTS**

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

25th EDITION

Department of Health and Human Services

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

2005

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

**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

25th EDITION

Cumulative Supplement 4

April 2005

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**APPROVED DRUG PRODUCTS
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25th EDITION

**CUMULATIVE SUPPLEMENT 4
April 2005**

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, 25th 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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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, are for military use, or 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 25th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 26th Edition. The current edition

Section 2. How To Use The Drug Product Lists describes the layout and usage of the List.

New additions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol >A>. The Patent and Exclusivity List new additions are indicated by the symbol >A> to the left of Patent Number or Exclusivity Code. The >A> 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.

The Patent and Exclusivity List is arranged in alphabetical order by active ingredient name(s) and trade name. The trade name will follow the active ingredient name separated by a dash symbol. 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. Drug substance and drug product patents are indicated as such with DS or DP in the Patent codes column. 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 B, in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations. Refer to Section 1.3 for internet access to the most current list of Patent and Exclusivity terms.

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. The Electronic Orange Book Query, updated monthly, will contain the most current applicant holder name.

FORMER APPLICANT NAME
(FORMER ABBREVIATED NAME)

NEW APPLICANT NAME
(NEW ABBREVIATED NAME)

CELLTECH PHARMACEUTICALS INC
(CELLTECH PHARMS
FUJISAWA HEALTHCARE

UCB PHARMA INC
(UCB)
ASTELLAS PHARMA US INC

(FUJISAWA HLTHCARE)
SHIRE LABORATORIES INC
(SHIRE LABS)
SHIRE PHARMACEUTICAL DEVELOPMENT INC
(SHIRE PHARM)
YAMANOUCHI PHARMA AMERICA INC
(YAMANOUCHI)

(ASTELLAS)
SHIRE DEVELOPMENT INC
(SHIRE)
SHIRE DEVELOPMENT INC
(SHIRE)
ASTELLAS PHARMA US INC
(ASTELLAS)

1.3 AVAILABILITY OF THE EDITION

Commencing with the 25th edition, the Annual Edition and monthly Cumulative Supplements will not be available in a published paper version.

Since 1997, the Electronic Orange Book (EOB <http://www.fda.gov/cder/ob/default.htm>), has been available on the internet and has become the updated-every-month Orange Book.

The 25th edition and current monthly supplement are available in an electronic downloadable Portable Document Format (PDF) at the EOB home page by clicking on the Annual Edition. The PDF annual and cumulative supplements will duplicate previous paper versions. Over time, there will be an archive for the annuals and each year's December Cumulative Supplement.

The Electronic Orange Book Query (EOB) is at <http://www.fda.gov/cder/ob/default.htm>. The Query provides searching of the approved drug list by active ingredient, proprietary name, applicant holder, applicant number or patent 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. Currently, In addition to monthly updates, in the public interest, the EOB is updated on a daily basis with new generic product approval information and new patent information. Current month updates are accomplished by the third week of the following month.

There are historical lists of Orange Book cumulative supplement product monthly changes at <http://www.fda.gov/cder/rxotcdpl/pdplarchive.htm>

There are ASCII text files of the Orange Book drug product, patent, and exclusivity data at <http://www.fda.gov/cder/orange/obreadme.htm>. The drug product text files are zipped into eobzip.exe. The files are updated concurrently with the monthly cumulative supplements. Appendix A and Appendix B text files of the annual Orange Book Edition are updated quarterly.

Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from the FDA Forms List, <http://www.fda.gov/opacom/morechoices/fdaforms/default.html>.

The current listing of the Orphan Product Designations and Approvals is available at <http://www.fda.gov/orphan/designat/list.htm>.

1.4 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 2004) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

DEFINITIONS

Drug Product

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

New Molecular Entity

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

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST COUNTS CUMULATIVE BY QUARTER

<u>CATEGORIES COUNTED</u>	<u>DEC 2004</u>	<u>MAR 2005</u>	<u>JUN 2005</u>	<u>SEP 2005</u>
DRUG PRODUCTS LISTED	11082	11184		
SINGLE SOURCE	2427 (21.9%)	2437 (21.8%)		
MULTISOURCE	8547 (77.1%)	8637 (77.2%)		
THERAPEUTICALLY EQUIVALENT	8327 (75.1%)	8428 (75.4%)		
NOT THERAPEUTICALLY EQUIVALENT	220 (2.0%)	209 (1.9%)		
EXCEPTIONS ¹	108 (1.0%)	110 (1.0%)		
NEW MOLECULAR ENTITIES APPROVED	9	2		
NUMBER OF APPLICANTS	625	631		

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

1.5 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 Application 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.
CAIN	Change. There has been a change in the Ingredient(s) name. All products will be deleted under the old name and all products will be added under the changed ingredient(s) name.
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 - 25TH EDITION

RX DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2005

1-1

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

		TABLET; ORAL			
		BUTALBITAL, APAP, AND CAFFEINE			
AB	WATSON LABS	325MG;50MG;40MG	N89536 001	Feb 16, 1988	Feb CAHN

ACETAMINOPHEN; TRAMADOL HYDROCHLORIDE

		TABLET; ORAL			
		ACETAMINOPHEN AND TRAMADOL HCL			
AB	KALI LABS	325MG;37.5MG	N76475 001	Apr 21, 2005	Mar NEWA
		ULTRACET			
AB	+ ORTHO MCNEIL PHARM	325MG;37.5MG	N21123 001	Aug 15, 2001	Mar CFTG

ACETIC ACID, GLACIAL

		SOLUTION/DROPS; OTIC			
		ACETIC ACID			
AT	+ MORTON GROVE	2%	N40166 001	Jul 26, 1996	Jan CRLD
AT	VINTAGE	2%	N40607 001	Feb 24, 2005	Feb NEWA
		VOSOL			
	@ MEDPOINTE PHARM HLC	2%	N12179 001		Jan DISC

ACRIVASTINE; PSEUDOEPHEDRINE HYDROCHLORIDE

		CAPSULE; ORAL			
		SEMPREX-D			
	+ UCB	8MG;60MG	N19806 001	Mar 25, 1994	Mar CAHN

ACYCLOVIR

		CAPSULE; ORAL			
		ACYCLOVIR			
AB	TEVA PHARMS	200MG	N74914 001	Nov 26, 1997	Mar CAHN
		TABLET; ORAL			
		ACYCLOVIR			
AB	TEVA PHARMS	400MG	N75021 001	Mar 18, 1998	Mar CAHN
AB		800MG	N75021 002	Mar 18, 1998	Mar CAHN

ACYCLOVIR SODIUM

		INJECTABLE; INJECTION			
		ACYCLOVIR			
	@ ABBOTT	EQ 50MG BASE/ML	N75114 001	Jul 26, 1999	Feb DISC

ADENOSINE

		INJECTABLE; INJECTION			
		ADENOSINE			
>A>	AP	AM PHARM	3MG/ML	N77133 001	Apr 27, 2005
				Apr	NEWA

ALBUTEROL SULFATE

		SOLUTION; INHALATION			
		ALBUTEROL SULFATE			
AN	+ DEY	EQ 0.083% BASE	N72652 001	Feb 21, 1992	Jan CRLD
		TABLET; ORAL			
		ALBUTEROL SULFATE			
>A>	AB	+ MYLAN	EQ 2MG BASE	N72894 002	Jan 17, 1991
				Apr	CMS1

ALENDRONATE SODIUMSOLUTION; ORAL
FOSAMAX

>D>	+	MERCK	EQ 70MG ACID/75ML	N21575 001	Sep 17, 2003	Apr	CPOT
>A>	+		EQ 70MG BASE/75ML	N21575 001	Sep 17, 2003	Apr	CPOT

ALENDRONATE SODIUM; CHOLECALCIFEROLTABLET; ORAL
FOSAMAX PLUS D

>A>	+	MERCK	EQ 70MG BASE;2,800 IU	N21762 001	Apr 07, 2005	Apr	NEWA
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ALPRAZOLAMTABLET, ORALLY DISINTEGRATING; ORAL
NIRAVAM

SCHWARZ PHARMA

0.25MG

N21726 001 Jan 19, 2005 Jan NEWA

0.5MG

N21726 002 Jan 19, 2005 Jan NEWA

1MG

N21726 003 Jan 19, 2005 Jan NEWA

+

2MG

N21726 004 Jan 19, 2005 Jan NEWA

ALPROSTADILINJECTABLE; INJECTION
EDEX

>D>	+	SCHWARZ PHARMA	0.01MG/VIAL	N20649 005	Jul 30, 1998	Apr	CTEC
>A>	AP	+	0.01MG/VIAL	N20649 005	Jul 30, 1998	Apr	CTEC
>D>	+		0.02MG/VIAL	N20649 006	Jul 30, 1998	Apr	CTEC
>A>	AP	+	0.02MG/VIAL	N20649 006	Jul 30, 1998	Apr	CTEC
>D>	+		0.04MG/VIAL	N20649 007	Jul 30, 1998	Apr	CTEC
>A>	AP	+	0.04MG/VIAL	N20649 007	Jul 30, 1998	Apr	CTEC

AMANTADINE HYDROCHLORIDESYRUP; ORAL
AMANTADINE HCL

AA TEVA PHARMS

50MG/5ML

N73115 001 Aug 23, 1991 Mar CAHN

AMINO ACIDS

INJECTABLE; INJECTION

AMINOSYN 7%

HOSPIRA

7% (7GM/100ML)

N17673 002 Mar CMFD

AMINOSYN 8.5%

HOSPIRA

8.5% (8.5GM/100ML)

N17673 004 Mar CMFD

AMIODARONE

INJECTABLE; INTRAVENOUS

AMIODARONE HCL

AP APOTEX

50MG/ML

N77161 001 Apr 20, 2005 Mar NEWA

AMIODARONE HYDROCHLORIDE

INJECTABLE; INJECTION

AMIODARONE HCL

AP + AM PHARM PARTNERS

50MG/ML

N75761 001 Oct 15, 2002 Mar CRLD

AP + APOTEX

50MG/ML

N76394 001 Apr 25, 2003 Mar CRLD

AP + BEDFORD

50MG/ML

N76018 001 Oct 15, 2002 Mar CRLD

AP + BEDFORD LABS

50MG/ML

N76299 001 Oct 24, 2002 Mar CRLD

AP + BEN VENUE

50MG/ML

N76088 001 Oct 15, 2002 Mar CRLD

AP + BIONICHE (CANADA)

50MG/ML

N76217 001 Oct 15, 2002 Mar CRLD

INJECTABLE; INJECTION

AMIODARONE HCL

AP	+	MAYNE PHARMA USA	50MG/ML	N76108 001	Oct 15, 2002	Mar	CRLD
AP	+	SICOR PHARMS	50MG/ML	N76163 001	Sep 05, 2003	Mar	CRLD

TABLET; ORAL

AMIODARONE HCL

AB		AUROSAL PHARMS	200MG	N77069 001	Apr 08, 2005	Mar	NEWA
AB			400MG	N77069 002	Apr 08, 2005	Mar	NEWA
AB		TARO	100MG	N75424 002	Dec 18, 2002	Mar	CTEC
AB		TEVA PHARMS	200MG	N74739 001	Nov 30, 1998	Mar	CAHN
PACERONE							
AB		UPSHER SMITH	100MG	N75135 002	Apr 12, 2005	Mar	NEWA

AMOXICILLIN

FOR SUSPENSION; ORAL

TRIMOX

>D>		@ APOTHECON	50MG/ML	N61886 001		Apr	CMFD
>A>	AB		50MG/ML	N61886 001		Apr	CMFD
>D>		@	125MG/5ML	N61886 002		Apr	CMFD
>A>	AB		125MG/5ML	N61886 002		Apr	CMFD
>D>		@	250MG/5ML	N61886 003		Apr	CMFD
>A>	AB		250MG/5ML	N61886 003		Apr	CMFD

AMOXICILLIN; CLAVULANATE POTASSIUM

FOR SUSPENSION; ORAL

AMOXICILLIN AND CLAVULANATE POTASSIUM

AB		HIKMA PHARMS	200MG/5ML;EQ 28.5MG BASE/5ML	N65191 002	Jan 25, 2005	Jan	NEWA
AB			400MG/5ML;EQ 57MG BASE/5ML	N65191 001	Jan 25, 2005	Jan	NEWA

TABLET, CHEWABLE; ORAL

AMOXICILLIN AND CLAVULANATE POTASSIUM

AB		TEVA	200MG;EQ 28.5MG BASE	N65205 001	Feb 09, 2005	Jan	NEWA
AB			400MG;EQ 57MG BASE	N65205 002	Feb 09, 2005	Jan	NEWA

AMPICILLIN SODIUM

INJECTABLE; INJECTION

AMPICILLIN SODIUM

AP		INSTITUTO BIOCHEMICO	EQ 125MG BASE/VIAL	N62797 001	Jul 12, 1993	Jan	CMFD
AP			EQ 2GM BASE/VIAL	N62797 002	Jul 12, 1993	Jan	CAHN

ANAGRELIDE HYDROCHLORIDE

CAPSULE; ORAL

AGRYLIN

AB		SHIRE	EQ 0.5MG BASE	N20333 001	Mar 14, 1997	Mar	CFTG
AB	+		EQ 1MG BASE	N20333 002	Mar 14, 1997	Mar	CFTG

ANAGRELIDE HCL

AB		BARR	EQ 0.5MG BASE	N76530 001	Apr 18, 2005	Mar	NEWA
AB			EQ 1MG BASE	N76530 002	Apr 18, 2005	Mar	NEWA
AB		EON	EQ 0.5MG BASE	N76683 001	Apr 18, 2005	Mar	NEWA
AB			EQ 1MG BASE	N76683 002	Apr 18, 2005	Mar	NEWA
AB		IMPAX LABS	EQ 0.5MG BASE	N76910 001	Apr 18, 2005	Mar	NEWA
AB			EQ 1MG BASE	N76910 002	Apr 18, 2005	Mar	NEWA
AB		IVAX PHARMS	EQ 0.5MG BASE	N76468 001	Apr 18, 2005	Mar	NEWA
AB			EQ 1MG BASE	N76468 002	Apr 18, 2005	Mar	NEWA
AB		MYLAN	EQ 0.5MG BASE	N76811 001	Apr 18, 2005	Mar	NEWA
AB			EQ 1MG BASE	N76811 002	Apr 18, 2005	Mar	NEWA
AB		ROXANE	EQ 0.5MG BASE	N76489 001	Apr 18, 2005	Mar	NEWA

CAPSULE; ORAL
ANAGRELIDE HCL

AB	ROXANE	EQ 1MG BASE	N76489 002	Apr 18, 2005	Mar	NEWA
AB	WATSON LABS	EQ 0.5MG BASE	N76417 001	Apr 18, 2005	Mar	NEWA
AB		EQ 1MG BASE	N76417 002	Apr 18, 2005	Mar	NEWA

ATENOLOLTABLET; ORAL
ATENOLOL

AB	MYLAN	25MG	N73457 002	Apr 26, 1999	Mar	CTEC
AB	TEVA PHARMS	50MG	N74120 001	Feb 24, 1995	Mar	CAHN
AB		100MG	N74120 002	Feb 24, 1995	Mar	CAHN
AB	ZYDUS PHARMS USA	25MG	N76900 001	Jan 28, 2005	Jan	NEWA
AB		50MG	N76900 002	Jan 28, 2005	Jan	NEWA
AB		100MG	N76900 003	Jan 28, 2005	Jan	NEWA

ATOMOXETINE HYDROCHLORIDECAPSULE; ORAL
STRATTERA
LILLY

	80MG	N21411 007	Feb 14, 2005	Feb	NEWA
	100MG	N21411 008	Feb 14, 2005	Feb	NEWA

BECLOMETHASONE DIPROPIONATE

AEROSOL, METERED; INHALATION

>D>	VANCERIL					
>D>	+ SCHERING	0.042MG/INH	N17573 001		Apr	DISC
>A>	@	0.042MG/INH	N17573 001		Apr	DISC

BENZYL PENICILLOYL-POLYLYSINEINJECTABLE; INJECTION
PRE-PEN

@ HOLLISTER STIER LABS	60UMOLAR	N50114 001		Mar	DISC
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BETAMETHASONE DIPROPIONATELOTION; TOPICAL
BETAMETHASONE DIPROPIONATE

AB	TEVA PHARMS	EQ 0.05% BASE	N71882 001	Jun 06, 1988	Mar	CAHN
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OINTMENT; TOPICAL

ALPHATREX						
@ SAVAGE LABS	EQ 0.05% BASE	N19143 001	Sep 04, 1984	Jan	DISC	

BETAMETHASONE VALERATELOTION; TOPICAL
BETAMETHASONE VALERATE

AB	TEVA PHARMS	EQ 0.1% BASE	N71883 001	Apr 22, 1988	Mar	CAHN
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BETHANECHOL CHLORIDETABLET; ORAL
DUVOID

>D>	@ WELLSRING PHARM	50MG	N85882 003		Apr	CMFD
>A>	AA	50MG	N85882 003		Apr	CMFD

BISOPROLOL FUMARATETABLET; ORAL
BISOPROLOL FUMARATE

AB	TEVA PHARMS	5MG	N75644 001	Jun 26, 2001	Mar	CAHN
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TABLET; ORAL							
BISOPROLOL FUMARATE							
AB	TEVA PHARMS	10MG		N75644 002	Jun 26, 2001	Mar	CAHN
<u>BROMFENAC SODIUM</u>							
SOLUTION/DROPS; OPHTHALMIC							
XIBROM							
	+ ISTA PHARMS	0.09%		N21664 001	Mar 24, 2005	Mar	NEWA
<u>BROMOCRIPTINE MESYLATE</u>							
CAPSULE; ORAL							
BROMOCRIPTINE MESYLATE							
AB	MYLAN	EQ 5MG BASE		N77226 001	Apr 04, 2005	Mar	NEWA
PARLODEL							
AB	+ NOVARTIS	EQ 5MG BASE		N17962 002	Mar 01, 1982	Mar	CTEC
<u>BUPRENORPHINE HYDROCHLORIDE</u>							
INJECTABLE; INJECTION							
BUPRENORPHINE HCL							
AP	BEDFORD	EQ 0.3MG BASE/ML		N76931 001	Mar 02, 2005	Feb	NEWA
<u>BUTENAFINE HYDROCHLORIDE</u>							
CREAM; TOPICAL							
MENTAX							
>D>	+ BERTEK PHARMS	1%		N20524 001	Oct 18, 1996	Apr	CAHN
>A>	+ MYLAN BERTEK	1%		N20524 001	Oct 18, 1996	Apr	CAHN
<u>CAFFEINE; ERGOTAMINE TARTRATE</u>							
SUPPOSITORY; RECTAL							
MIGERGOT							
BR	G AND W LABS	100MG;2MG		N86557 001	Oct 04, 1983	Feb	CMFD
<u>CAPTOPRIL</u>							
TABLET; ORAL							
CAPTOPRIL							
AB	TEVA PHARMS	12.5MG		N74462 001	Feb 13, 1996	Mar	CAHN
AB		25MG		N74462 002	Feb 13, 1996	Mar	CAHN
AB		50MG		N74462 003	Feb 13, 1996	Mar	CAHN
AB		100MG		N74462 004	Feb 13, 1996	Mar	CAHN
<u>CARBAMAZEPINE</u>							
SUSPENSION; ORAL							
CARBAMAZEPINE							
	@ TARO	100MG/5ML		N75875 001	Dec 21, 2000	Mar	DISC
<u>CARBOPLATIN</u>							
INJECTABLE; INJECTION							
CARBOPLATIN							
AP	EON	50MG/VIAL		N76959 001	Mar 18, 2005	Mar	NEWA
AP		150MG/VIAL		N76959 002	Mar 18, 2005	Mar	NEWA
AP		450MG/VIAL		N76959 003	Mar 18, 2005	Mar	NEWA
<u>CEFACLOR</u>							
CAPSULE; ORAL							
CECLOR							
	@ LILLY	EQ 250MG BASE		N50521 001		Mar	DISC

CAPSULE; ORAL

CECLOR

@ LILLY

EQ 500MG BASE

N50521 002

Mar DISC

CEFACLOR

AB + RANBAXY

EQ 500MG BASE

N64156 002 Aug 28, 1997 Mar CRLD

FOR SUSPENSION; ORAL

>D>

CECLOR

>D>

AB CEPH INTL

EQ 125MG BASE/5ML

N62206 001

Apr CTNA

>D>

AB

EQ 187MG BASE/5ML

N62206 003

Apr 20, 1988 Apr CTNA

>D>

AB

EQ 250MG BASE/5ML

N62206 002

Apr CTNA

>D>

AB

EQ 375MG BASE/5ML

N62206 004

Apr 20, 1988 Apr CTNA

AB

EQ 375MG BASE/5ML

N62206 004

Apr 20, 1988 Mar CRLD

@ LILLY

EQ 125MG BASE/5ML

N50522 001

Mar DISC

@

EQ 250MG BASE/5ML

N50522 002

Mar DISC

>A>

CEFACLOR

>A>

AB CEPH INTL

EQ 125MG BASE/5ML

N62206 001

Apr CTNA

>A>

AB

EQ 187MG BASE/5ML

N62206 003

Apr 20, 1988 Apr CTNA

>A>

AB

EQ 250MG BASE/5ML

N62206 002

Apr CTNA

>A>

AB

EQ 375MG BASE/5ML

N62206 004

Apr 20, 1988 Apr CTNA

AB + RANBAXY

EQ 375MG BASE/5ML

N64155 001 Oct 02, 1997 Mar CRLD

CEFADROXIL/CEFADROXIL HEMIHYDRATE

TABLET; ORAL

CEFADROXIL

>D>

@ IVAX PHARMS

EQ 1GM BASE

N62774 001 Apr 08, 1987 Apr CMFD

>A>

AB

EQ 1GM BASE

N62774 001 Apr 08, 1987 Apr CMFD

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

CEFAZOLIN SODIUM

AP + AM PHARM PARTNERS

EQ 500MG BASE/VIAL

N64169 001 Aug 14, 1998 Mar CRLD

AP

+

EQ 1GM BASE/VIAL

N64169 002 Aug 14, 1998 Mar CRLD

AP

+

EQ 10GM BASE/VIAL

N64170 001 Mar 18, 1998 Mar CRLD

>A>

AP

ORCHID HLTHCARE

EQ 500MG BASE/VIAL

N65226 001 Apr 21, 2005 Apr NEWA

>A>

AP

EQ 1GM BASE/VIAL

N65226 002 Apr 21, 2005 Apr NEWA

CEFTRIAXONE SODIUM

INJECTABLE; IM-IV

CEFTRIAXONE

>A>

AP

SANDOZ

EQ 250MG BASE/VIAL

N65169 001 May 09, 2005 Apr NEWA

>A>

AP

EQ 500MG BASE/VIAL

N65169 002 May 09, 2005 Apr NEWA

>A>

AP

EQ 1GM BASE/VIAL

N65169 003 May 09, 2005 Apr NEWA

>A>

AP

EQ 2GM BASE/VIAL

N65169 004 May 09, 2005 Apr NEWA

INJECTABLE; INJECTION

CEFTRIAXONE

>A>

AP

SANDOZ

EQ 1GM BASE/VIAL

N65204 001 May 03, 2005 Apr NEWA

>A>

AP

EQ 2GM BASE/VIAL

N65204 002 May 03, 2005 Apr NEWA

>A>

AP

EQ 10GM BASE/VIAL

N65168 001 May 17, 2005 Apr NEWA

>A>

AP

CEFTRIAXONE AND DEXTROSE IN DUPLEX CONTAINER

>A>

AP

+

B BRAUN

EQ 1GM BASE/VIAL

N50796 001 Apr 20, 2005 Apr NEWA

>A>

AP

+

EQ 2GM BASE/VIAL

N50796 002 Apr 20, 2005 Apr NEWA

ROCEPHIN

>D>

HLR

EQ 250MG BASE/VIAL

N63239 001 Aug 13, 1993 Apr DISC

>A>

@

EQ 250MG BASE/VIAL

N63239 001 Aug 13, 1993 Apr DISC

>D>

HLR

EQ 500MG BASE/VIAL

N63239 002 Aug 13, 1993 Apr DISC

>A>

@

EQ 500MG BASE/VIAL

N63239 002 Aug 13, 1993 Apr DISC

>D>

+

EQ 1GM BASE/VIAL

N62654 002 Apr 30, 1987 Apr CFTG

INJECTABLE; INJECTION
ROCEPHIN

>A>	AP	+	HLR	EQ 1GM BASE/VIAL	N62654 002	Apr 30, 1987	Apr	CFTG
		+		EQ 1GM BASE/VIAL	N62654 002	Apr 30, 1987	Mar	CRLD
>D>				EQ 1GM BASE/VIAL	N63239 003	Aug 13, 1993	Apr	DISC
>A>			@	EQ 1GM BASE/VIAL	N63239 003	Aug 13, 1993	Apr	DISC
>D>				EQ 2GM BASE/VIAL	N62654 003	Apr 30, 1987	Apr	CFTG
>A>	AP	+		EQ 2GM BASE/VIAL	N62654 003	Apr 30, 1987	Apr	CFTG
>D>		+		EQ 10GM BASE/VIAL	N50585 005	Dec 21, 1984	Apr	CFTG
>A>	AP	+		EQ 10GM BASE/VIAL	N50585 005	Dec 21, 1984	Apr	CFTG

CEFUROXIME SODIUM

INJECTABLE; INJECTION
CEFUROXIME AND DEXTROSE IN DUPLEX CONTAINER

>D>		+	B BRAUN	EQ 15MG BASE/ML	N50780 001	Feb 21, 2001	Apr	CPOT
>A>	AP	+		EQ 750MG BASE/VIAL	N50780 001	Feb 21, 2001	Apr	CPOT
>D>		+		EQ 30MG BASE/ML	N50780 002	Feb 21, 2001	Apr	CPOT
>A>	AP	+		EQ 1.5GM BASE/VIAL	N50780 002	Feb 21, 2001	Apr	CPOT

CEPHALEXIN

CAPSULE; ORAL
CEPHALEXIN

			@ APOTHECON	EQ 250MG BASE	N63186 001	Dec 30, 1994	Mar	DISC
			@	EQ 500MG BASE	N63186 002	Dec 30, 1994	Mar	DISC
AB			BELCHER	EQ 250MG BASE	N62713 001	Jul 15, 1988	Jan	CAHN
AB				EQ 500MG BASE	N62713 002	Jul 15, 1988	Jan	CAHN
AB			SUN PHARM INDS (IN)	EQ 250MG BASE	N62791 001	Jun 11, 1987	Jan	CAHN
AB				EQ 500MG BASE	N62791 002	Jun 11, 1987	Jan	CAHN
AB			YUNG SHIN PHARM	EQ 250MG BASE	N65152 001	Feb 24, 2005	Feb	NEWA
AB				EQ 500MG BASE	N65152 002	Feb 24, 2005	Feb	NEWA

CHLORPHENIRAMINE POLISTIREX; CODEINE POLISTIREX

SUSPENSION, EXTENDED RELEASE; ORAL
CODEPREX

+	UCB	EQ 4MG MALEATE/5ML;EQ 20MG BASE/5ML	N21369 001	Jun 21, 2004	Mar	CAHN
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CHLORPHENIRAMINE POLISTIREX; HYDROCODONE POLISTIREX

SUSPENSION, EXTENDED RELEASE; ORAL
TUSSIONEX

+	UCB	EQ 8MG MALEATE/5ML;EQ 10MG BITARTRATE/5ML	N19111 001	Dec 31, 1987	Mar	CAHN
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CHLORPROMAZINE HYDROCHLORIDE

TABLET; ORAL
CHLORPROMAZINE HCL

>D>	BP		SANDOZ	10MG	N80439 001		Apr	CRLD
>A>	BP	+		10MG	N80439 001		Apr	CRLD
>D>	BP			100MG	N80439 004		Apr	CRLD
>A>	BP	+		100MG	N80439 004		Apr	CRLD
>D>			THORAZINE					
>D>	BP	+	GLAXOSMITHKLINE	10MG	N09149 002		Apr	DISC
>A>			@	10MG	N09149 002		Apr	DISC
>D>	BP			25MG	N09149 007		Apr	DISC
>A>			@	25MG	N09149 007		Apr	DISC
>D>	BP			50MG	N09149 013		Apr	DISC
>A>			@	50MG	N09149 013		Apr	DISC

	TABLET; ORAL					
>D>		THORAZINE				
>D>	BP	+ GLAXOSMITHKLINE	100MG	N09149 018	Apr	DISC
>A>		@	100MG	N09149 018	Apr	DISC
>D>	BP		200MG	N09149 020	Apr	DISC
>A>		@	200MG	N09149 020	Apr	DISC

CHOLESTYRAMINE

	POWDER; ORAL					
	CHOLESTYRAMINE					
AB	TEVA PHARMS	EQ 4GM RESIN/PACKET	N74554 001	Oct 02, 1996	Mar	CAHN
AB		EQ 4GM RESIN/SC00PFUL	N74554 002	Oct 02, 1996	Mar	CAHN
	CHOLESTYRAMINE LIGHT					
AB	TEVA PHARMS	EQ 4GM RESIN/PACKET	N74555 001	Sep 30, 1998	Mar	CAHN
AB		EQ 4GM RESIN/SC00PFUL	N74555 002	Sep 30, 1998	Mar	CAHN

CICLOPIROX

	CREAM; TOPICAL					
	CICLOPIROX					
AB	TARO	0.77%	N76790 001	Apr 12, 2005	Mar	NEWA

CILOSTAZOL

	TABLET; ORAL					
	CILOSTAZOL					
AB	COREPHARMA	50MG	N77150 001	Mar 11, 2005	Feb	NEWA
AB	IVAX PHARMS	100MG	N77020 002	Mar 01, 2005	Feb	NEWA
>A>	AB	ROXANE	N77024 001	May 17, 2005	Apr	NEWA
>A>	AB		N77024 002	May 17, 2005	Apr	NEWA

CIMETIDINE HYDROCHLORIDE

	SOLUTION; ORAL					
	CIMETIDINE HCL					
AA	TEVA PHARMS	EQ 300MG BASE/5ML	N74859 001	Jul 09, 1998	Mar	CAHN

CIPROFLOXACIN HYDROCHLORIDE

	SOLUTION/DROPS; OPHTHALMIC					
	CIPROFLOXACIN					
AT	HITECH PHARMA	EQ 0.3% BASE	N76673 001	Jan 21, 2005	Jan	NEWA
	TABLET; ORAL					
	CIPROFLOXACIN					
AB	COBALT	EQ 100MG BASE	N76794 001	Feb 10, 2005	Jan	NEWA
AB	SANDOZ	EQ 100MG BASE	N75939 001	Mar 03, 2005	Feb	NEWA
AB	TARO	EQ 100MG BASE	N76912 001	Feb 18, 2005	Jan	NEWA

CITALOPRAM HYDROBROMIDE

	TABLET; ORAL					
	CITALOPRAM HYDROBROMIDE					
>A>	AB	AKYMA PHARMS	EQ 10MG BASE	N77045 003	Apr 29, 2005	Apr
>A>	AB		EQ 20MG BASE	N77045 002	Apr 29, 2005	Apr
>A>	AB		EQ 40MG BASE	N77045 001	Apr 29, 2005	Apr
	AB	MYLAN	EQ 10MG BASE	N77039 001	Feb 03, 2005	Jan
	AB		EQ 20MG BASE	N77039 002	Feb 03, 2005	Jan
	AB		EQ 40MG BASE	N77039 003	Feb 03, 2005	Jan

CLARITHROMYCIN

TABLET, EXTENDED RELEASE; ORAL

CLARITHROMYCIN

>A>	AB	RANBAXY	1GM	N65210 001	Jan 26, 2005	Jan	NEWA
	AB	TEVA	500MG	N65154 001	May 18, 2005	Apr	NEWA

TABLET; ORAL

CLARITHROMYCIN

	AB	GENPHARM	250MG	N65195 001	Mar 11, 2005	Feb	NEWA
	AB		500MG	N65195 002	Mar 11, 2005	Feb	NEWA

CLEMASTINE FUMARATE

SYRUP; ORAL

CLEMASTINE FUMARATE

AA		TEVA PHARMS	EQ 0.5MG BASE/5ML	N73095 001	Apr 21, 1992	Mar	CAHN
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CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL

CLINDAMYCIN HYDROCHLORIDE

AB		ZYDUS PHARMS USA	EQ 75MG BASE	N65217 001	Jan 31, 2005	Jan	NEWA
AB			EQ 150MG BASE	N65217 002	Jan 31, 2005	Jan	NEWA
AB			EQ 300MG BASE	N65217 003	Jan 31, 2005	Jan	NEWA

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION

CLINDAMYCIN PHOSPHATE

AP		HOSPIRA	EQ 150MG BASE/ML	N62943 001	Sep 29, 1988	Mar	CMFD
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CLOBETASOL PROPIONATE

CREAM; TOPICAL

CLOBETASOL PROPIONATE

AB1		TEVA PHARMS	0.05%	N74087 001	Feb 16, 1994	Mar	CAHN
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OINTMENT; TOPICAL

CLOBETASOL PROPIONATE

AB		TEVA PHARMS	0.05%	N74089 001	Feb 16, 1994	Mar	CAHN
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CLONAZEPAM

TABLET; ORAL

CLONAZEPAM

>A>	AB	KALI LABS	0.5MG	N77147 001	May 02, 2005	Apr	NEWA
>A>	AB		1MG	N77147 002	May 02, 2005	Apr	NEWA
>A>	AB		2MG	N77147 003	May 02, 2005	Apr	NEWA

CLOTRIMAZOLE

CREAM; TOPICAL

CLOTRIMAZOLE

+	TARO	1%	N72640 001	Aug 31, 1993	Feb	CRLD
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LOTRIMIN

@	SCHERING PLOUGH	1%	N17619 001		Feb	DISC
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MYCELEX

@	BAYER PHARMS	1%	N18183 001		Feb	DISC
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CLOZAPINE

TABLET; ORAL

CLOZAPINE

>A>		IVAX PHARMS	50MG	N74949 004	Apr 25, 2005	Apr	NEWA
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		TABLET; ORAL							
		CLOZAPINE							
>A>	AB	TEVA	25MG	N75162 001	Apr 26, 2005	Apr	NEWA		
>A>	AB		100MG	N75162 002	Apr 26, 2005	Apr	NEWA		
		<u>CROMOLYN SODIUM</u>							
		SOLUTION, CONCENTRATE; ORAL							
		GASTROCROM							
	+	UCB	100MG/5ML	N20479 001	Feb 29, 1996	Mar	CAHN		
		<u>CYANOCOBALAMIN</u>							
		SPRAY, METERED; NASAL							
		NASCOBAL							
	+	NASTECH PHARM	0.5MG/SPRAY	N21642 001	Jan 31, 2005	Jan	NEWA		
	+	QUESTCOR PHARMS	0.5MG/SPRAY	N21642 001	Jan 31, 2005	Feb	CAHN		
		<u>CYCLOSPORINE</u>							
		CAPSULE; ORAL							
		CYCLOSPORINE							
AB1		IVAX PHARMS	25MG	N65110 003	Mar 29, 2005	Mar	NEWA		
AB1			50MG	N65110 001	Mar 29, 2005	Mar	NEWA		
AB1			100MG	N65110 002	Mar 29, 2005	Mar	NEWA		
		GENGRAF							
AB1		ABBOTT	50MG	N65003 002	May 12, 2000	Mar	CTEC		
		SOLUTION; ORAL							
		CYCLOSPORINE							
AB1		IVAX PHARMS	100MG/ML	N65078 001	Mar 25, 2005	Mar	NEWA		
		<u>CYPROHEPTADINE HYDROCHLORIDE</u>							
		TABLET; ORAL							
		CYPROHEPTADINE HCL							
	@	ABC HOLDING	4MG	N88212 001	May 26, 1983	Feb	DISC		
		<u>DALTEPARIN SODIUM</u>							
		INJECTABLE; INJECTION							
		FRAGMIN							
	+	PHARMACIA AND UPJOHN	7,500 IU/0.3ML	N20287 005	Apr 04, 2002	Jan	NEWA		
>A>	@		7,500 IU/0.75ML	N20287 008	Apr 04, 2002	Apr	DISC		
>A>	+		95,000IU/3.8ML (25,000IU/ML)	N20287 006	Apr 04, 2002	Apr	NEWA		
>A>	+		95,000IU/9.5ML (10,000IU/ML)	N20287 007	Apr 04, 2002	Apr	NEWA		
		<u>DANTROLENE SODIUM</u>							
		CAPSULE; ORAL							
		DANTRIUM							
AB		PROCTER AND GAMBLE	25MG	N17443 001		Feb	CFTG		
AB			50MG	N17443 003		Feb	CFTG		
AB	+		100MG	N17443 002		Feb	CFTG		
		DANTROLENE SODIUM							
AB		IMPAX LABS	25MG	N76856 001	Mar 01, 2005	Feb	NEWA		
AB			50MG	N76856 002	Mar 01, 2005	Feb	NEWA		
AB			100MG	N76856 003	Mar 01, 2005	Feb	NEWA		
		<u>DESIRUDIN RECOMBINANT</u>							
		INJECTABLE; SUBCUTANEOUS							
		IPRIVASK							
	+	CANYON	15MG/VIAL	N21271 001	Apr 04, 2003	Mar	CAIN		

DESLORATADINE; PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE; ORAL
CLARINEX D 24 HOUR

+ SCHERING 5MG;240MG N21605 001 Mar 03, 2005 Mar NEWA

DESMOPRESSIN ACETATE

SPRAY, METERED; NASAL
DESMOPRESSIN ACETATE (NEEDS NO REFRIGERATION)

AB APOTEX 0.01MG/SPRAY N76703 001 Jan 27, 2005 Jan NEWA

DESONIDE

CREAM; TOPICAL
DESONIDE

AB TEVA PHARMS 0.05% N74027 001 Sep 28, 1992 Mar CAHN

DEXAMETHASONE

TABLET; ORAL
DEXAMETHASONE

PAR PHARM 0.25MG N88149 001 Apr 28, 1983 Mar CRLD
BP ROXANE 1.5MG N84610 001 Mar CRLD

DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION
DEXAMETHASONE SODIUM PHOSPHATE

>A> AP AM PHARM EQ 10MG PHOSPHATE/ML N40572 001 Apr 22, 2005 Apr NEWA

DEXTROSE

INJECTABLE; INJECTION
DEXTROSE 50% IN PLASTIC CONTAINER

AP HOSPIRA 500MG/ML N19445 001 Jun 03, 1986 Mar CMFD

DIAZEPAM

GEL; RECTAL
DIASTAT

>A> VALEANT 2.5MG/0.5ML N20648 001 Jul 29, 1997 Apr CAHN
>A> 5MG/ML N20648 002 Jul 29, 1997 Apr CAHN
>A> 10MG/2ML N20648 003 Jul 29, 1997 Apr CAHN
>A> 15MG/3ML N20648 004 Jul 29, 1997 Apr CAHN
>A> + 20MG/4ML N20648 005 Jul 29, 1997 Apr CAHN
>D> XCEL PHARMS 2.5MG/0.5ML N20648 001 Jul 29, 1997 Apr CAHN
>D> 5MG/ML N20648 002 Jul 29, 1997 Apr CAHN
>D> 10MG/2ML N20648 003 Jul 29, 1997 Apr CAHN
>D> 15MG/3ML N20648 004 Jul 29, 1997 Apr CAHN
>D> + 20MG/4ML N20648 005 Jul 29, 1997 Apr CAHN

DICLOFENAC SODIUM

TABLET, DELAYED RELEASE; ORAL
DICLOFENAC SODIUM

AB TEVA PHARMS 25MG N74459 001 Jun 25, 1997 Mar CAHN
AB 50MG N74459 002 Jun 25, 1997 Mar CAHN
AB 75MG N74459 003 Jun 25, 1997 Mar CAHN

DICYCLOMINE HYDROCHLORIDE

SYRUP; ORAL							
BENTYL							
AA	+	AXCAN SCANDIPHARM	10MG/5ML	N07961 002	Oct 15, 1984	Mar	CTEC
DICYCLOMINE HCL							
AA		MIKART	10MG/5ML	N40169 001	Mar 24, 2005	Mar	NEWA

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL							
DIETHYLPROPION HCL							
		@ ABC HOLDING	25MG	N88267 001	Aug 25, 1983	Feb	DISC
		@	25MG	N88268 001	Aug 25, 1983	Feb	DISC
TENUATE							
	+	AVENTIS PHARMS	25MG	N11722 002		Feb	CTEC

DIHYDROERGOTAMINE MESYLATE

INJECTABLE; INJECTION							
D.H.E. 45							
>A>	AP	+	VALEANT	1MG/ML	N05929 001	Apr	CAHN
>D>	AP	+	XCEL PHARMS	1MG/ML	N05929 001	Apr	CAHN
SPRAY, METERED; NASAL							
MIGRANAL							
>A>		+	VALEANT	0.5MG/INH	N20148 001	Dec 08, 1997	Apr CAHN
>D>		+	XCEL PHARM	0.5MG/INH	N20148 001	Dec 08, 1997	Apr CAHN

DILTIAZEM HYDROCHLORIDE

INJECTABLE; INJECTION							
CARDIZEM							
AP	+	BIOVAIL LABS INTL	5MG/ML	N20027 001	Oct 24, 1991	Mar	CAHN
	+		25MG/VIAL	N20027 003	Aug 18, 1995	Mar	CAHN
TABLET, EXTENDED RELEASE; ORAL							
CARDIZEM LA							
		BIOVAIL LABS INTL	120MG	N21392 001	Feb 06, 2003	Mar	CAHN
			180MG	N21392 002	Feb 06, 2003	Mar	CAHN
			240MG	N21392 003	Feb 06, 2003	Mar	CAHN
			300MG	N21392 004	Feb 06, 2003	Mar	CAHN
			360MG	N21392 005	Feb 06, 2003	Mar	CAHN
		+	420MG	N21392 006	Feb 06, 2003	Mar	CAHN
TABLET; ORAL							
CARDIZEM							
AB		BIOVAIL LABS INTL	30MG	N18602 001	Nov 05, 1982	Mar	CAHN
AB			60MG	N18602 002	Nov 05, 1982	Mar	CAHN
AB			90MG	N18602 003	Dec 08, 1986	Mar	CAHN
AB	+		120MG	N18602 004	Dec 08, 1986	Mar	CAHN
DILTIAZEM HCL							
AB		TEVA PHARMS	30MG	N74067 001	Nov 05, 1992	Mar	CAHN
AB			60MG	N74067 002	Nov 05, 1992	Mar	CAHN
AB			90MG	N74067 003	Nov 05, 1992	Mar	CAHN
AB			120MG	N74067 004	Nov 05, 1992	Mar	CAHN

DOXAZOSIN MESYLATE

TABLET, EXTENDED RELEASE; ORAL							
CARDURA XL							
		PFIZER	EQ 4MG BASE	N21269 001	Feb 22, 2005	Feb	NEWA
	+		EQ 8MG BASE	N21269 002	Feb 22, 2005	Feb	NEWA

DOXEPIN HYDROCHLORIDE

	CONCENTRATE; ORAL					
	DOXEPIN HCL					
AA	TEVA PHARMS	EQ 10MG BASE/ML	N71609	001	Nov 09, 1987	Mar CAHN

DOXYCYCLINE

	CAPSULE; ORAL					
	DOXYCYCLINE					
AB	PAR PHARM	EQ 75MG BASE	N65055	004	Apr 18, 2005	Mar NEWA
AB	RANBAXY	EQ 75MG BASE	N65053	003	Sep 10, 2003	Mar CTEC

DOXYCYCLINE HYCLATE

	CAPSULE; ORAL					
	DOXYCYCLINE HYCLATE					
>A>	+ WEST WARD	EQ 20MG BASE	N65103	001	May 13, 2005	Apr NEWA
	TABLET; ORAL					
	DOXYCYCLINE HYCLATE					
>A>	AB COREPHARMA	EQ 20MG BASE	N65182	001	May 13, 2005	Apr NEWA
>A>	AB IVAX PHARMS	EQ 20MG BASE	N65163	001	May 13, 2005	Apr NEWA
>A>	AB MUTUAL PHARMA	EQ 20MG BASE	N65134	001	May 13, 2005	Apr NEWA
	PERIOSTAT					
>D>	+ COLLAGENEX PHARMS	20MG	N50783	001	Feb 02, 2001	Apr CFTG
>A>	AB +	EQ 20MG BASE	N50783	001	Feb 02, 2001	Apr CFTG

ENALAPRIL MALEATE

	TABLET; ORAL					
	ENALAPRIL MALEATE					
	@ APOTHECON	2.5MG	N75583	001	Aug 22, 2000	Feb DISC
	@	5MG	N75583	002	Aug 22, 2000	Feb DISC
	@	10MG	N75583	003	Aug 22, 2000	Feb DISC
	@	20MG	N75583	004	Aug 22, 2000	Feb DISC
	VASOTEC					
AB	BIOVAIL LABS INTL	2.5MG	N18998	005	Jul 26, 1988	Mar CAHN
AB		5MG	N18998	001	Dec 24, 1985	Mar CAHN
AB		10MG	N18998	002	Dec 24, 1985	Mar CAHN
AB	+	20MG	N18998	003	Dec 24, 1985	Mar CAHN

ENALAPRIL MALEATE; HYDROCHLOROTHIAZIDE

	TABLET; ORAL					
	VASERETIC					
AB	BIOVAIL LABS INTL	5MG;12.5MG	N19221	003	Jul 12, 1995	Mar CAHN
AB	+	10MG;25MG	N19221	001	Oct 31, 1986	Mar CAHN

ENALAPRILAT

	INJECTABLE; INJECTION					
	VASOTEC					
AP	+ BIOVAIL LABS INTL	1.25MG/ML	N19309	001	Feb 09, 1988	Mar CAHN

ENTECAVIR

	SOLUTION; ORAL					
	BARACLUDE					
	+ BRISTOL MYERS SQUIBB	0.05MG/ML	N21798	001	Mar 29, 2005	Mar NEWA
	TABLET; ORAL					
	BARACLUDE					
	BRISTOL MYERS SQUIBB	0.5MG	N21797	001	Mar 29, 2005	Mar NEWA

TABLET; ORAL
BARACLUDE

+ BRISTOL MYERS SQUIBB 1MG N21797 002 Mar 29, 2005 Mar NEWA

EPINEPHRINE

INJECTABLE; IM-SC
TWINJECT 0.30

+ HOLLISTER STIER LABS EQ 0.3MG /DELIVERY N20800 001 May 30, 2003 Feb CTNA

ERYTHROMYCIN

SOLUTION; TOPICAL
ERYMAX

AT MERZ PHARMS 2% N62508 002 Jul 11, 1985 Jan CAHN

ERYTHROMYCIN ESTOLATE

CAPSULE; ORAL
ERYTHROMYCIN ESTOLATE
@ BARR

EQ 250MG BASE N62162 002 Feb DISC

ESMOLOL HYDROCHLORIDE

INJECTABLE; INJECTION
ESMOLOL HCL

>A> AP AM PHARM 10MG/ML N76573 001 May 02, 2005 Apr NEWA

>A> AP PHARMAFORCE 10MG/ML N76474 001 May 02, 2005 Apr NEWA

ESOMEPRAZOLE MAGNESIUM

CAPSULE, DELAYED REL PELLETS; ORAL
NEXIUM

ASTRAZENECA EQ 20MG BASE N21153 001 Feb 20, 2001 Jan CRLD

ESOMEPRAZOLE SODIUM

INJECTABLE; INTRAVENOUS
NEXIUM IV

+ ASTRAZENECA 20MG/VIAL N21689 001 Mar 31, 2005 Mar NEWA

+ 40MG/VIAL N21689 002 Mar 31, 2005 Mar NEWA

ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL
CLIMARA

AB2 + BERLEX 0.025MG/24HR N20375 004 Mar 05, 1999 Jan CFTG

AB2 + 0.075MG/24HR N20375 003 Mar 23, 1998 Jan CFTG

ESCLIM

@ WOMEN FIRST HLTHCARE 0.025MG/24HR N20847 001 Aug 04, 1998 Jan DISC

@ 0.0375MG/24HR N20847 002 Aug 04, 1998 Jan DISC

@ 0.05MG/24HR N20847 003 Aug 04, 1998 Jan DISC

@ 0.075MG/24HR N20847 004 Aug 04, 1998 Jan DISC

@ 0.1MG/24HR N20847 005 Aug 04, 1998 Jan DISC

ESTRADIOL

AB2 MYLAN TECHNOLOGIES 0.025MG/24HR N75182 003 Jan 26, 2005 Jan NEWA

AB2 0.075MG/24HR N75182 002 Jan 26, 2005 Jan NEWA

VIVELLE

@ NOVARTIS 0.025MG/24HR N20323 005 Aug 16, 2000 Jan DISC

AB1 0.05MG/24HR N20323 002 Oct 28, 1994 Jan CRLD

AB1 0.1MG/24HR N20323 004 Oct 28, 1994 Jan CRLD

VIVELLE-DOT

BX + NOVARTIS 0.025MG/24HR N20538 009 May 03, 2002 Jan CRLD

FILM, EXTENDED RELEASE; TRANSDERMAL
VIVELLE-DOT

BX	+	NOVARTIS	0.0375MG/24HR	N20538 005	Jan 08, 1999	Jan	CRLD
AB1	+		0.05MG/24HR	N20538 006	Jan 08, 1999	Jan	CRLD
BX	+		0.075MG/24HR	N20538 007	Jan 08, 1999	Jan	CRLD
AB1	+		0.1MG/24HR	N20538 008	Jan 08, 1999	Jan	CRLD

ESTRADIOL; NORGESTIMATE

TABLET; ORAL

>A>		ESTRADIOL AND NORGESTIMATE					
>A>	AB	BARR	1MG, 1MG; N/A, 0.09MG	N76812 001	Apr 29, 2005	Apr	NEWA
		PREFEST					
>D>	+	DURAMED	1MG, 1MG; 0.09MG, N/A	N21040 001	Oct 22, 1999	Apr	CFTG
>A>	AB	+	1MG, 1MG; N/A, 0.09MG	N21040 001	Oct 22, 1999	Apr	CFTG

ESTROGENS, CONJUGATED SYNTHETIC B

TABLET; ORAL

ENJUVIA

@	DURAMED	0.3MG	N21443 001	Dec 20, 2004	Mar	DISC
@		0.45MG	N21443 002	Dec 20, 2004	Mar	DISC

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

NORETHINDRONE AND ETHINYL ESTRADIOL (7/14)

+	WATSON LABS	0.035MG, 0.035MG; 0.5MG, 1MG	N71041 001	Sep 24, 1991	Mar	CTEC
	NORTREL 7/7/7					
	BARR	0.035MG, 0.035MG, 0.035MG; 0.5MG, 0.75MG, 1MG	N75478 001	Aug 30, 2002	Mar	CTEC

TABLET; ORAL-28

NORETHINDRONE AND ETHINYL ESTRADIOL (7/14)

	WATSON LABS	0.035MG, 0.035MG; 0.5MG, 1MG	N71042 001	Sep 24, 1991	Mar	CTEC	
	ORTHO-NOVUM 10/11-28						
AB	+	ORTHO MCNEIL PHARM	0.035MG, 0.035MG; 0.5MG, 1MG	N18354 002	Jan 11, 1982	Mar	CRLD
	ORTHO-NOVUM 7/14-28						
	@ ORTHO MCNEIL PHARM	0.035MG, 0.035MG; 0.5MG, 1MG	N19004 002	Apr 04, 1984	Feb	DISC	
	OVCON-35						
AB	WARNER CHILCOTT	0.035MG; 0.4MG	N17716 001		Mar	CRLD	

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

TABLET; ORAL-28

NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE

>A>	AB	ANDRX PHARMS	0.03MG; 1.5MG	N77075 001	Apr 28, 2005	Apr	NEWA
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ETHOSUXIMIDE

SYRUP; ORAL

ETHOSUXIMIDE

AA		TEVA PHARMS	250MG/5ML	N81306 001	Jul 30, 1993	Mar	CAHN
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>A> EXENATIDE SYNTHETIC

>A> INJECTABLE; SUBCUTANEOUS

>A> BYETTA

>A>	+	AMYLIN	300UGM/1.2ML (250UGM/ML)	N21773 001	Apr 28, 2005	Apr	NEWA
>A>	+		600UGM/2.4ML (250UGM/ML)	N21773 002	Apr 28, 2005	Apr	NEWA

FENOFIBRATE

TABLET; ORAL

>A> FENOFIBRATE

>A>	AB	TEVA	54MG	N76433 001	May 13, 2005	Apr	NEWA
>A>	AB		160MG	N76433 002	May 13, 2005	Apr	NEWA

TRICOR

>D>		ABBOTT	54MG	N21203 001	Sep 04, 2001	Apr	CFTG
>A>	AB		54MG	N21203 001	Sep 04, 2001	Apr	CFTG
>D>		+	160MG	N21203 003	Sep 04, 2001	Apr	CFTG
>A>	AB	+	160MG	N21203 003	Sep 04, 2001	Apr	CFTG

FENOLDOPAM MESYLATE

INJECTABLE; INJECTION

FENOLDOPAM MESYLATE

AP		SABEX 2002	EQ 10MG BASE/ML	N77155 001	Feb 15, 2005	Jan	NEWA
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FENOPROFEN CALCIUM

CAPSULE; ORAL

NALFON

>A>	AB	+	PEDINOL	EQ 300MG BASE	N17604 002		Apr	CAHN
>D>	AB	+	RANBAXY	EQ 300MG BASE	N17604 002		Apr	CAHN
			NALFON 200					
>A>	AB		PEDINOL	EQ 200MG BASE	N17604 003		Apr	CAHN
>D>	AB		RANBAXY	EQ 200MG BASE	N17604 003		Apr	CAHN

FENTANYL

FILM, EXTENDED RELEASE; TRANSDERMAL

DURAGESIC-100

AB		ALZA	100UGM/HR	N19813 001	Aug 07, 1990	Jan	CFTG
		DURAGESIC-12					
		ALZA	12.5UGM/HR	N19813 005	Feb 04, 2005	Feb	NEWA
		DURAGESIC-25					
AB	+	ALZA	25UGM/HR	N19813 004	Aug 07, 1990	Jan	CFTG
		DURAGESIC-50					
AB		ALZA	50UGM/HR	N19813 003	Aug 07, 1990	Jan	CFTG
		DURAGESIC-75					
AB		ALZA	75UGM/HR	N19813 002	Aug 07, 1990	Jan	CFTG
		FENTANYL					
AB		MYLAN TECHNOLOGIES	25UGM/HR	N76258 001	Jan 28, 2005	Jan	NEWA
AB			50UGM/HR	N76258 002	Jan 28, 2005	Jan	NEWA
AB			75UGM/HR	N76258 003	Jan 28, 2005	Jan	NEWA
AB			100UGM/HR	N76258 004	Jan 28, 2005	Jan	NEWA

FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

ALLEGRA-D 12 HOUR

AB	+	AVENTIS PHARMS	60MG;120MG	N20786 001	Dec 24, 1997	Mar	CFTG
		FEXOFENADINE HCL AND PSEUDOEPHEDRINE HCL					
AB		BARR	60MG;120MG	N76236 001	Apr 14, 2005	Mar	NEWA

FLUCONAZOLE

INJECTABLE; INJECTION

FLUCONAZOLE IN DEXTROSE 5% IN PLASTIC CONTAINER

AP		APOTEX	200MG/100ML	N76888 001	Mar 25, 2005	Mar	NEWA
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INJECTABLE; INJECTION

FLUCONAZOLE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP	APOTEX	200MG/100ML	N76889 001	Mar 25, 2005	Mar	NEWA
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FLUCYTOSINE

CAPSULE; ORAL

ANCOBON

>D>	ICN	250MG	N17001 001		Apr	CAHN
>D>	+	500MG	N17001 002		Apr	CAHN
>A>	VALEANT	250MG	N17001 001		Apr	CAHN
>A>	+	500MG	N17001 002		Apr	CAHN

FLUMAZENIL

INJECTABLE; INJECTION

FLUMAZENIL

>A>	AP	SABEX 2002	0.5MG/5ML (0.1MG/ML)	N77071 001	May 03, 2005	Apr	NEWA
>A>	AP		1MG/10ML (0.1MG/ML)	N77071 002	May 03, 2005	Apr	NEWA

FLUOCINOLONE ACETONIDE

>A>	IMPLANT; INTRAVITREAL					
>A>	RETISERT					
>A>	+ BAUSCH AND LOMB	0.59MG	N21737 001	Apr 08, 2005	Apr	NEWA

FLUOCINONIDE

CREAM; TOPICAL

VANOS

+ MEDICIS

0.1%

N21758 001 Feb 11, 2005 Feb NEWA

SOLUTION; TOPICAL

FLUOCINONIDE

AT	TEVA PHARMS	0.05%	N72522 001	Sep 28, 1990	Mar	CAHN
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FLUOROURACIL

INJECTABLE; INJECTION

FLUOROURACIL

>D>	AP	+ ICN PUERTO RICO	50MG/ML	N12209 001		Apr	CAHN
>A>	AP	+ VALEANT	50MG/ML	N12209 001		Apr	CAHN

FLUOXETINE HYDROCHLORIDE

CAPSULE; ORAL

FLUOXETINE

>A>	AB	BARR	EQ 40MG BASE	N76251 001	May 18, 2005	Apr	NEWA
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FLUPHENAZINE HYDROCHLORIDE

CONCENTRATE; ORAL

FLUPHENAZINE HCL

AA	TEVA PHARMS	5MG/ML	N73058 001	Aug 30, 1991	Mar	CAHN
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ELIXIR; ORAL

FLUPHENAZINE HCL

AA	TEVA PHARMS	2.5MG/5ML	N81310 001	Apr 29, 1993	Mar	CAHN
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FLUTICASONE PROPIONATE

AEROSOL, METERED; INHALATION

FLOVENT

+ GLAXOSMITHKLINE

0.044MG/INH

N20548 001 Mar 27, 1996 Jan CRLD

+

0.11MG/INH

N20548 002 Mar 27, 1996 Jan CRLD

AEROSOL, METERED; INHALATION

FLOVENT HFA

+	GLAXOSMITHKLINE	0.044MG/INH	N21433 003	May 14, 2004	Jan	CRLD
+		0.11MG/INH	N21433 002	May 14, 2004	Jan	CRLD

LOTION; TOPICAL

CUTIVATE

+	GLAXOSMITHKLINE	0.05%	N21152 001	Mar 31, 2005	Mar	NEWA
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FOLLITROPIN ALFA/BETA

INJECTABLE; SUBCUTANEOUS

FOLLISTIM AQ

+	ORGANON USA INC	150 IU/0.18ML	N21211 003	Feb 11, 2004	Feb	NEWA
+		300 IU/0.36ML	N21211 001	Mar 23, 2004	Jan	CPOT
+		600 IU/0.72ML	N21211 002	Mar 23, 2004	Jan	CPOT
+		900 IU/1.08ML	N21211 004	Feb 11, 2005	Feb	NEWA

FOMIVIRSEN SODIUM

INJECTABLE; INJECTION

VITRAVENE PRESERVATIVE FREE

@	NOVARTIS	6.6MG/ML	N20961 001	Aug 26, 1998	Feb	DISC
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FOSINOPRIL SODIUM

TABLET; ORAL

FOSINOPRIL SODIUM

>A>	AB	APOTEX	10MG	N76906 001	May 17, 2005	Apr	NEWA
>A>	AB		20MG	N76906 002	May 17, 2005	Apr	NEWA
>A>	AB		40MG	N76906 003	May 17, 2005	Apr	NEWA
	AB	INVAGEN PHARMS	10MG	N77222 001	Apr 20, 2005	Mar	NEWA
	AB		20MG	N77222 002	Apr 20, 2005	Mar	NEWA
	AB		40MG	N77222 003	Apr 20, 2005	Mar	NEWA

FUROSEMIDE

INJECTABLE; INJECTION

FUROSEMIDE

AP	+	LUITPOLD	10MG/ML	N18579 001	Nov 30, 1983	Feb	CRLD
		LASIX					
		@ AVENTIS PHARMS	10MG/ML	N16363 001		Feb	DISC

GABAPENTIN

CAPSULE; ORAL

GABAPENTIN

AB		APOTEX	100MG	N75360 001	Apr 06, 2005	Mar	NEWA
AB			300MG	N75360 002	Apr 06, 2005	Mar	NEWA
AB			400MG	N75360 003	Apr 06, 2005	Mar	NEWA
AB		EON	100MG	N75539 001	Apr 06, 2005	Mar	NEWA
AB			300MG	N75539 002	Apr 06, 2005	Mar	NEWA
AB			400MG	N75539 003	Apr 06, 2005	Mar	NEWA
AB		IVAX PHARMS	100MG	N75477 001	Mar 23, 2005	Mar	NEWA
AB			300MG	N75477 002	Mar 23, 2005	Mar	NEWA
AB			400MG	N75477 003	Mar 23, 2005	Mar	NEWA

TABLET; ORAL

GABAPENTIN

>A>	AB	IVAX PHARMS	600MG	N76017 004	Apr 29, 2005	Apr	NEWA
>A>	AB		800MG	N76017 005	Apr 29, 2005	Apr	NEWA

GALANTAMINE HYDROBROMIDECAPSULE, EXTENDED RELEASE; ORAL
REMINYL

+	JOHNSON AND JOHNSON	EQ 8MG BASE	N21615 001	Dec 22, 2004	Jan	CRLD
		EQ 24MG BASE	N21615 003	Dec 22, 2004	Jan	CRLD

GATIFLOXACININJECTABLE; INJECTION
TEQUIN

+	BRISTOL MYERS SQUIBB	400MG/40ML(10MG/ML)	N21062 004	Dec 17, 1999	Mar	CPOT
	TEQUIN IN DEXTROSE 5% IN PLASTIC CONTAINER					
+	BRISTOL MYERS SQUIBB	200MG/100ML(2MG/ML)	N21062 001	Dec 17, 1999	Mar	CPOT
+		400MG/200ML(2MG/ML)	N21062 002	Dec 17, 1999	Mar	CPOT

GLYBURIDE; METFORMIN HYDROCHLORIDETABLET; ORAL
GLYBURIDE AND METFORMIN HCL

AB	TEVA	1.25MG;250MG	N76821 001	Jan 27, 2005	Jan	NEWA
AB		2.5MG;500MG	N76821 002	Jan 27, 2005	Jan	NEWA
AB		5MG;500MG	N76821 003	Jan 27, 2005	Jan	NEWA

GLYCOPYRROLATETABLET; ORAL
GLYCOPYRROLATE

>D>	AB	COREPHARMA	1MG	N40568 001	Dec 22, 2004	Apr	CTEC
>A>	AA		1MG	N40568 001	Dec 22, 2004	Apr	CTEC
>D>	AB		2MG	N40568 002	Dec 22, 2004	Apr	CTEC
>A>	AA		2MG	N40568 002	Dec 22, 2004	Apr	CTEC
		ROBINUL					
>D>	AB	+	FIRST HORIZON	1MG	N12827 001	Apr	CTEC
>A>	AA	+		1MG	N12827 001	Apr	CTEC
		ROBINUL FORTE					
>D>	AB	+	FIRST HORIZON	2MG	N12827 002	Apr	CTEC
>A>	AA	+		2MG	N12827 002	Apr	CTEC

GONADOTROPIN, CHORIONICINJECTABLE; INJECTION
CHORIONIC GONADOTROPIN

	@	WATSON LABS (UTAH)	2,000 UNITS/VIAL	N17016 009	Dec 27, 1984	Feb	CAHN
	@		2,000 UNITS/VIAL	N17016 011	Feb 16, 1990	Feb	CAHN
	@		5,000 UNITS/VIAL	N17016 006		Feb	CAHN
AP	+		10,000 UNITS/VIAL	N17016 007		Feb	CAHN
	@		15,000 UNITS/VIAL	N17016 010	Feb 15, 1985	Feb	CAHN
	@		20,000 UNITS/VIAL	N17016 004		Feb	CAHN

GRISEOFULVIN, MICROCRYSTALLINESUSPENSION; ORAL
GRIFULVIN V

AB	+	J AND J	125MG/5ML	N62483 001	Jan 26, 1984	Feb	CFTG
		GRISEOFULVIN					
AB		STIEFEL	125MG/5ML	N65200 001	Mar 02, 2005	Feb	NEWA

GUANABENZ ACETATE

TABLET; ORAL

GUANABENZ ACETATE

AB	TEVA PHARMS	EQ 4MG BASE	N74267 001	Jun 01, 1994	Mar	CAHN
AB		EQ 8MG BASE	N74267 002	Jun 01, 1994	Mar	CAHN

HALOPERIDOL LACTATE

CONCENTRATE; ORAL

HALOPERIDOL

AA	+	TEVA PHARMS	EQ 2MG BASE/ML	N71617 001	Dec 01, 1988	Mar	CAHN
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HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE

SYRUP; ORAL

HYDROCODONE BITARTRATE AND HOMATROPINE METHYLBROMIDE

AA		IVAX PHARMS	1.5MG/5ML;5MG/5ML	N40285 001	Jul 19, 1999	Jan	CAHN
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HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

HYDRALAZINE HCL

@ ABC HOLDING

10MG

N88846 001 Feb 26, 1985 Feb DISC

@

25MG

N88847 001 Feb 26, 1985 Feb DISC

@

50MG

N88848 001 Feb 26, 1985 Feb DISC

@

100MG

N88849 001 Feb 26, 1985 Feb DISC

HYDROCHLOROTHIAZIDE

TABLET; ORAL

HYDROCHLOROTHIAZIDE

@ ABC HOLDING

25MG

N85683 001 Feb DISC

@

50MG

N83965 001 Feb DISC

@

50MG

N85672 001 Feb DISC

>D>	AB	IVAX PHARMS	50MG	N83177 002	Apr	CRLD
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>A>	AB	+	50MG	N83177 002	Apr	CRLD
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>D>	AB	+	100MG	N85022 001	Apr	DISC
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>A>		@	100MG	N85022 001	Apr	DISC
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HYDROCHLOROTHIAZIDE; IRBESARTAN

TABLET; ORAL

AVALIDE

SANOFI SYNTHELABO

12.5MG;300MG

N20758 003 Aug 31, 1998 Mar CRLD

+

25MG;300MG

N20758 004 Mar 15, 2005 Mar NEWA

HYDROCHLOROTHIAZIDE; QUINAPRIL HYDROCHLORIDE

TABLET; ORAL

QUINAPRIL HCL AND HYDROCHLOROTHIAZIDE

AB	MYLAN	12.5MG;EQ 10MG BASE	N77093 001	Mar 28, 2005	Mar	NEWA
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AB		12.5MG;EQ 20MG BASE	N77093 002	Mar 28, 2005	Mar	NEWA
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AB		25MG;EQ 20MG BASE	N77093 003	Mar 28, 2005	Mar	NEWA
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HYDROCHLOROTHIAZIDE; VALSARTAN

TABLET; ORAL

DIOVAN HCT

NOVARTIS

12.5MG;160MG

N20818 002 Mar 06, 1998 Mar CRLD

+

25MG;160MG

N20818 003 Jan 17, 2002 Mar CRLD

HYDROCORTISONE

	ENEMA; RECTAL						
	HYDROCORTISONE						
AB	TEVA PHARMS	100MG/60ML	N74171	001	May 27, 1994	Mar	CAHN

HYDROCORTISONE VALERATE

	CREAM; TOPICAL						
	HYDROCORTISONE VALERATE						
AB	TEVA PHARMS	0.2%	N74489	001	Aug 12, 1998	Mar	CAHN

HYDROMORPHONE HYDROCHLORIDE

	CAPSULE, EXTENDED RELEASE; ORAL						
	PALLADONE						
	PURDUE PHARMA LP	16MG	N21044	002	Sep 24, 2004	Feb	CRLD
	+	32MG	N21044	004	Sep 24, 2004	Feb	CRLD

HYDROXYCHLOROQUINE SULFATE

	TABLET; ORAL						
	HYDROXYCHLOROQUINE SULFATE						
AB	TEVA PHARMS	200MG	N40081	001	Sep 30, 1994	Mar	CAHN

HYDROXYPROGESTERONE CAPROATE

	INJECTABLE; INJECTION						
	HYDROXYPROGESTERONE CAPROATE						
	@ WATSON LABS	125MG/ML	N17439	001		Mar	CAHN
	@	250MG/ML	N17439	002		Mar	CAHN

IBANDRONATE SODIUM

	TABLET; ORAL						
	BONIVA						
	+	ROCHE	EQ 2.5MG BASE	N21455	001	May 16, 2003	Feb CMFD
>D>			EQ 150MG BASE	N21455	002	Mar 24, 2005	Apr CRLD
>A>			EQ 150MG BASE	N21455	002	Mar 24, 2005	Apr CRLD
			EQ 150MG BASE	N21455	002	Mar 24, 2005	Mar NEWA

IMIPRAMINE HYDROCHLORIDE

	TABLET; ORAL						
	IMIPRAMINE HCL						
	@ TEVA	10MG	N83729	001		Feb	DISC
	@	25MG	N83729	004		Feb	DISC
	@	50MG	N83729	003		Feb	DISC

IPRATROPIUM BROMIDE

	SOLUTION; INHALATION						
	IPRATROPIUM BROMIDE						
>A>	AN	BREATH LTD	0.02%	N76291	001	May 09, 2005	Apr NEWA

IRON DEXTRAN

	INJECTABLE; INJECTION						
	INFED						
BP	+	WATSON LABS (UTAH)	EQ 50MG IRON/ML	N17441	001	Feb	CAHN

IRON SUCROSE

INJECTABLE; INTRAVENOUS
VENOFER

+	LUITPOLD	EQ 100MG BASE/5ML(EQ 20MG BASE/ML)	N21135 001	Nov 06, 2000	Mar	CPOT
		EQ 50MG BASE/2.5ML(EQ 20MG BASE/ML)	N21135 002	Mar 20, 2005	Mar	NEWA
		EQ 75MG BASE/3.75ML(EQ 20MG BASE/ML)	N21135 003	Mar 29, 2005	Mar	NEWA

ISRADIPINE

TABLET, EXTENDED RELEASE; ORAL
DYNACIRC CR
RELIANT PHARMS

5MG

N20336 001 Jun 01, 1994 Mar CRLD

KANAMYCIN SULFATE

CAPSULE; ORAL

KANTREX

@ APOTHECON

EQ 500MG BASE

N62726 001 Mar 06, 1987 Feb DISC

KETOCONAZOLE

SHAMPOO; TOPICAL

KETOCONAZOLE

AB

QLT USA

2%

N76942 001 Apr 11, 2005 Mar NEWA

LACTULOSE

SOLUTION; ORAL

EVALOSE

AA

TEVA PHARMS

10GM/15ML

N73497 001 May 28, 1993 Mar CAHN

SOLUTION; ORAL, RECTAL

HEPTALAC

AA

TEVA PHARMS

10GM/15ML

N73504 001 May 28, 1993 Mar CAHN

LEPIRUDIN RECOMBINANT

INJECTABLE; INJECTION

REFLUDAN

+ BERLEX

50MG/VIAL

N20807 001 Mar 06, 1998 Mar CAIN

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION

LEUCOVORIN CALCIUM PRESERVATIVE FREE

>D>

AP

BEDFORD

EQ 10MG BASE/ML

N40347 001 Apr 25, 2000 Apr CRLD

>A>

AP

+

EQ 10MG BASE/ML

N40347 001 Apr 25, 2000 Apr CRLD

>D>

AP

+

HOSPIRA

EQ 10MG BASE/ML

N40147 001 Jun 25, 1997 Apr DISC

>A>

@

EQ 10MG BASE/ML

N40147 001 Jun 25, 1997 Apr DISC

LEUPROLIDE ACETATE

INJECTABLE; SUBCUTANEOUS

ELIGARD

+ QLT USA

22.5MG/VIAL

N21379 001 Jul 24, 2002 Jan CAHN

LEVALBUTEROL TARTRATE

AEROSOL, METERED; INHALATION

XOPENEX HFA

+ SEPRACOR

EQ 0.045MG BASE/INH

N21730 001 Mar 11, 2005 Mar NEWA

LEVOFLOXACIN

TABLET; ORAL

LEVAQUIN

		ORTHO MCNEIL PHARM	250MG	N20634 001	Dec 20, 1996	Mar	CTEC
			500MG	N20634 002	Dec 20, 1996	Mar	CTEC
AB	+		750MG	N20634 003	Sep 08, 2000	Jan	CFTG
		LEVOFLOXACIN					
AB		TEVA	750MG	N76361 003	Jan 26, 2005	Jan	NEWA

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HCL PRESERVATIVE FREE

>A>	AP	AM PHARM	2%	N17584 001		Apr	CAHN
>A>	AP		4%	N17584 002		Apr	CAHN
>D>	AP	AM PHARM PARTNERS	2%	N17584 001		Apr	CAHN
>D>	AP		4%	N17584 002		Apr	CAHN

JELLY; TOPICAL

LIDOCAINE HCL

AT		TEVA PHARMS	2%	N81318 001	Apr 29, 1993	Mar	CAHN
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LORAZEPAM

SOLUTION; ORAL

LORAZEPAM

ROXANE 0.5MG/5ML

N74648 001	Mar 18, 1997	Jan	CMFD
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MAFENIDE ACETATE

CREAM; TOPICAL

SULFAMYLON

>D>	+	BERTEK PHARMS	EQ 85MG BASE/GM	N16763 001		Apr	CAHN
>A>	+	MYLAN BERTEK	EQ 85MG BASE/GM	N16763 001		Apr	CAHN

MANGAFODIPIR TRISODIUM

INJECTABLE; INJECTION

TESLASCAN

@ GE HEALTHCARE 37.9MG/ML

N20652 001	Nov 26, 1997	Jan	DISC
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MEBENDAZOLE

TABLET, CHEWABLE; ORAL

MEBENDAZOLE

AB		TEVA PHARMS	100MG	N73580 001	Jan 04, 1995	Mar	CAHN
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MECLIZINE HYDROCHLORIDE

TABLET; ORAL

MECLIZINE HCL

@ ABC HOLDING 12.5MG

N85253 001		Feb	DISC
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@ 25MG

N85252 001		Feb	DISC
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MEGESTROL ACETATE

SUSPENSION; ORAL

MEGESTROL ACETATE

AB		TEVA PHARMS	40MG/ML	N75681 001	May 05, 2003	Mar	CAHN
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MEMANTINE HYDROCHLORIDE

>A>	SOLUTION; ORAL					
>A>	NAMENDA					
>A>	+ FOREST LABS	2MG/ML	N21627	001	Apr 18, 2005	Apr NEWA

MEQUINOL; TRETINOIN

	SOLUTION; TOPICAL					
	SOLAGE					
	+ BARRIER	2%;0.01%	N20922	001	Dec 10, 1999	Feb CAHN

METAPROTERENOL SULFATE

	SYRUP; ORAL					
	METAPROTERENOL SULFATE					
	@ TEVA PHARMS	10MG/5ML	N73034	001	Aug 30, 1991	Mar CAHN

METFORMIN HYDROCHLORIDE

	TABLET, EXTENDED RELEASE; ORAL					
	METFORMIN HCL					
AB	ANDRX PHARMS	750MG	N76869	001	Apr 12, 2005	Mar NEWA
AB	PUREPAC PHARM	750MG	N76878	001	Apr 13, 2005	Mar NEWA
AB	TEVA	750MG	N76864	001	Apr 12, 2005	Mar NEWA
AB	ZYDUS PHARMS USA	500MG	N77060	001	Apr 20, 2005	Mar NEWA
>A> AB		750MG	N77078	001	Apr 21, 2005	Apr NEWA
	TABLET; ORAL					
	METFORMIN HCL					
AB	ZYDUS PHARMS USA	500MG	N77064	001	Apr 18, 2005	Mar NEWA
AB		850MG	N77064	002	Apr 18, 2005	Mar NEWA
AB		1GM	N77064	003	Apr 18, 2005	Mar NEWA

METHAZOLAMIDE

	TABLET; ORAL					
	METHAZOLAMIDE					
AB	TEVA PHARMS	25MG	N40001	001	Jun 30, 1993	Mar CAHN
AB		50MG	N40001	002	Jun 30, 1993	Mar CAHN

METHIMAZOLE

	TABLET; ORAL					
	METHIMAZOLE					
AB	CEDAR PHARMS	5MG	N40547	001	Feb 18, 2005	Jan NEWA
AB		10MG	N40547	002	Feb 18, 2005	Jan NEWA
AB		20MG	N40547	004	Feb 18, 2005	Jan NEWA
>D> AB	+ GENPHARM	20MG	N40350	003	Jun 07, 2001	Apr DISC
>A>	@	20MG	N40350	003	Jun 07, 2001	Apr DISC
AB	+	20MG	N40350	003	Jun 07, 2001	Jan CFTG

METHOTREXATE SODIUM

	INJECTABLE; INJECTION					
	METHOTREXATE					
>D> AP	BIGMAR BIOREN PHARMS	EQ 25MG BASE/ML	N40263	001	Feb 26, 1999	Apr DISC
>A>	@	EQ 25MG BASE/ML	N40263	001	Feb 26, 1999	Apr DISC
>A> AP	+ MAYNE PHARMA USA	EQ 50MG BASE/2ML (25 MG/ML)	N11719	010	Dec 15, 2004	Apr NEWA
	METHOTREXATE LPF					
>D> AP	+ MAYNE PHARMA USA	EQ 25MG BASE/ML	N11719	007	Mar 31, 1982	Apr DISC
>A>	@	EQ 25MG BASE/ML	N11719	007	Mar 31, 1982	Apr DISC

INJECTABLE; INJECTION

METHOTREXATE PRESERVATIVE FREE

>D>	AP	BIGMAR BIOREN PHARMS	EQ 25MG BASE/ML	N40265 001	Feb 26, 1999	Apr	DISC
>A>		@	EQ 25MG BASE/ML	N40265 001	Feb 26, 1999	Apr	DISC
>D>	AP		EQ 1GM BASE/VIAL	N40266 001	Feb 26, 1999	Apr	DISC
>A>		@	EQ 1GM BASE/VIAL	N40266 001	Feb 26, 1999	Apr	DISC
>A>	+	MAYNE PHARMA USA	EQ 20MG BASE/2ML (10 MG/ML)	N11719 014	Apr 13, 2005	Apr	NEWA
>A>	AP	+	EQ 500MG BASE/20ML (25 MG/ML)	N11719 013	Apr 13, 2005	Apr	NEWA
>A>	AP	+	ED 1GM BASE/40ML (25 MG/ML)	N11719 012	Apr 13, 2005	Apr	NEWA
>A>	AP	+	EQ 2.5GM BASE/100ML (25 MG/ML)	N11719 011	Apr 13, 2005	Apr	NEWA

METHOTREXATE SODIUM

>D>	AP	BEDFORD	EQ 25MG BASE/ML	N89340 001	Sep 16, 1986	Apr	CPOT
>A>	AP		EQ 50 MG BASE/2ML (25 ML/ML)	N89340 001	Sep 16, 1986	Apr	CPOT
>D>	AP		EQ 25MG BASE/ML	N89341 001	Sep 16, 1986	Apr	CPOT
>A>	AP		EQ 100MG BASE/4ML (25 MG/ML)	N89341 001	Sep 16, 1986	Apr	CPOT
>D>	AP		EQ 25MG BASE/ML	N89342 001	Sep 16, 1986	Apr	CPOT
>A>	AP		EQ 200MG BASE/8ML (25 MG/ML)	N89342 001	Sep 16, 1986	Apr	CPOT
>D>	AP		EQ 25MG BASE/ML	N89343 001	Sep 16, 1986	Apr	CPOT
>A>	AP		EQ 250MG BASE/10ML (25 MG/ML)	N89343 001	Sep 16, 1986	Apr	CPOT
		@ MAYNE PHARMA USA	EQ 20MG BASE/VIAL	N11719 001		Mar	DISC
>D>	AP	+	EQ 25MG BASE/ML	N11719 005		Apr	DISC
>A>		@	EQ 25MG BASE/ML	N11719 005		Apr	DISC
>D>	AP	NORBROOK	EQ 25MG BASE/ML	N88648 001	May 09, 1986	Apr	DISC
>A>		@	EQ 25MG BASE/ML	N88648 001	May 09, 1986	Apr	DISC
>D>	AP	PHARMACHEMIE USA	EQ 25MG BASE/ML	N89158 001	Jul 08, 1988	Apr	DISC
>A>		@	EQ 25MG BASE/ML	N89158 001	Jul 08, 1988	Apr	DISC
		MEXATE-AQ					
>D>	AP	BRISTOL MYERS	EQ 25MG BASE/ML	N88760 001	Feb 14, 1985	Apr	DISC
>A>		@	EQ 25MG BASE/ML	N88760 001	Feb 14, 1985	Apr	DISC

METHYLDOPA

TABLET; ORAL

ALDOMET

@ MERCK

500MG

N13400 002

Jan DISC

METHYLDOPA

AB + MYLAN 500MG

N70076 001 Apr 18, 1985 Jan CRLD

METHYLDOPATE HYDROCHLORIDE

INJECTABLE; INJECTION

ALDOMET

@ MERCK

50MG/ML

N13401 001

Jan DISC

METHYLDOPATE HCL

AP + LUITPOLD 50MG/ML

N71279 001 Oct 02, 1987 Jan CRLD

METHYLERGONOVINE MALEATE

TABLET; ORAL

METHERGINE

+ NOVARTIS 0.2MG

N06035 003

Jan CRLD

METHYLPREDNISOLONE ACETATE

INJECTABLE; INJECTION

DEPO-MEDROL

AB + PHARMACIA AND UPJOHN 40MG/ML

N11757 001

Feb CFTG

AB + 80MG/ML

N11757 004

Feb CFTG

METHYLPREDNISOLONE ACETATE

AB SICOR PHARMS 40MG/ML

N40557 001 Feb 23, 2005 Feb NEWA

AB 80MG/ML

N40557 002 Feb 23, 2005 Feb NEWA

METOLAZONE

	TABLET; ORAL					
	ZAROXOLYN					
AB	UCB	2.5MG	N17386 001		Mar	CAHN
AB	+	5MG	N17386 002		Mar	CAHN
AB	+	10MG	N17386 003		Mar	CAHN

METOPROLOL TARTRATE

	TABLET; ORAL					
	METOPROLOL TARTRATE					
AB	TEVA PHARMS	50MG	N74333 001	Jan 27, 1994	Mar	CAHN
AB		100MG	N74333 002	Jan 27, 1994	Mar	CAHN

MICAFUNGIN SODIUM

INJECTABLE; IV (INFUSION)
MYCAMINE

+	ASTELLAS	50MG/VIAL	N21506 002	Mar 16, 2005	Mar	NEWA
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MIDAZOLAM HYDROCHLORIDE

INJECTABLE; INJECTION
MIDAZOLAM HCL

AP	HOSPIRA	EQ 1MG BASE/ML	N75293 001	Jun 20, 2000	Mar	CMFD
AP		EQ 5MG BASE/ML	N75293 002	Jun 20, 2000	Mar	CMFD
AP	INTL MEDICATED	EQ 1MG BASE/ML	N76144 001	Jan 26, 2005	Jan	NEWA
AP		EQ 5MG BASE/ML	N76144 002	Jan 26, 2005	Jan	NEWA

SYRUP; ORAL
MIDAZOLAM HCL

>A>	AA	PADDOCK	EQ 2MG BASE/ML	N76379 001	May 02, 2005	Apr	NEWA
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MOMETASONE FUROATE

CREAM; TOPICAL
ELOCON

AB	+	SCHERING	0.1%	N19625 001	May 06, 1987	Jan	CFTG
	MOMETASONE FUROATE						
AB		ALTANA	0.1%	N76171 001	Apr 08, 2005	Mar	NEWA
AB		TARO	0.1%	N76679 001	Dec 21, 2004	Jan	NEWA

LOTION; TOPICAL
ELOCON

AB	+	SCHERING	0.1%	N19796 001	Mar 30, 1989	Mar	CFTG
	MOMETASONE FUROATE						
AB		AGIS INDS	0.1%	N77180 001	Apr 06, 2005	Mar	NEWA

OINTMENT; TOPICAL
MOMETASONE FUROATE

AB		ALTANA	0.1%	N77061 001	Mar 28, 2005	Mar	NEWA
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POWDER; INHALATION
ASMANEX TWISTHALER

+	SCHERING	0.22MG/INH	N21067 001	Mar 30, 2005	Mar	NEWA
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MOMETASONE FUROATE MONOHYDRATE

SPRAY, METERED; NASAL
NASONEX

>A>	+	SCHERING PLOUGH	EQ 0.05MG BASE/SPRAY	N20762 001	Oct 01, 1997	Apr	CAHN
>D>	+	SHIRE	EQ 0.05MG BASE/SPRAY	N20762 001	Oct 01, 1997	Apr	CAHN
	+		EQ 0.05MG BASE/SPRAY	N20762 001	Oct 01, 1997	Mar	CAHN

MORPHINE SULFATECAPSULE, EXTENDED RELEASE; ORAL
AVINZA

BX	LIGAND	30MG	N21260 001	Mar 20, 2002	Mar	CRLD
BX		60MG	N21260 002	Mar 20, 2002	Mar	CRLD
		90MG	N21260 003	Mar 20, 2002	Mar	CRLD

KADIAN

	ALPHARMA US PHARMS	20MG	N20616 001	Jul 03, 1996	Mar	CRLD
BX		30MG	N20616 004	Mar 09, 2001	Mar	CRLD
		50MG	N20616 002	Jul 03, 1996	Mar	CRLD
BX		60MG	N20616 005	Mar 09, 2001	Mar	CRLD

NADOLOL

TABLET; ORAL

NADOLOL

AB	TEVA PHARMS	80MG	N74368 001	Aug 31, 1994	Mar	CAHN
AB		120MG	N74368 002	Aug 31, 1994	Mar	CAHN
AB		160MG	N74368 003	Aug 31, 1994	Mar	CAHN

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION

NALOXONE HCL

AP	HOSPIRA	0.4MG/ML	N70172 001	Sep 24, 1986	Mar	CMFD
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NAPROXEN

TABLET; ORAL

NAPROXEN

>A>	AB	PERRIGO R AND D	250MG	N77339 001	Apr 27, 2005	Apr	NEWA
>A>	AB		375MG	N77339 002	Apr 27, 2005	Apr	NEWA
>A>	AB		500MG	N77339 003	Apr 27, 2005	Apr	NEWA
	AB	TEVA PHARMS	250MG	N74207 001	Dec 21, 1993	Mar	CAHN
	AB		375MG	N74207 002	Dec 21, 1993	Mar	CAHN
	AB		500MG	N74207 003	Dec 21, 1993	Mar	CAHN

NAPROXEN SODIUM

TABLET; ORAL

NAPROXEN SODIUM

AB	TEVA PHARMS	EQ 250MG BASE	N74289 001	Jan 27, 1994	Mar	CAHN
AB		EQ 500MG BASE	N74289 002	Jan 27, 1994	Mar	CAHN

>D> NESIRITIDE

>D> FOR SOLUTION; INTRAVENOUS

>D> NATRECOR

>D>	+	SCIOS	1.5MG/VIAL	N20920 001	Aug 10, 2001	Apr	CAIN
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>A> NESIRITIDE RECOMBINANT

>A> FOR SOLUTION; INTRAVENOUS

>A> NATRECOR

>A>	+	SCIOS	1.5MG/VIAL	N20920 001	Aug 10, 2001	Apr	CAIN
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NIACIN

TABLET, EXTENDED RELEASE; ORAL

NIACIN

>A>	AB	BARR	500MG	N76378 001	Apr 26, 2005	Apr	NEWA
>A>	AB		750MG	N76378 002	Apr 26, 2005	Apr	NEWA

TABLET, EXTENDED RELEASE; ORAL							
>A>	NIACIN						
	AB	BARR	1GM	N76250	001	Apr 14, 2005	Mar NEWA
NIASPAN							
>D>	+	KOS	500MG	N20381	002	Jul 28, 1997	Apr CFTG
>A>	AB	+	500MG	N20381	002	Jul 28, 1997	Apr CFTG
>D>	+		750MG	N20381	003	Jul 28, 1997	Apr CFTG
>A>	AB	+	750MG	N20381	003	Jul 28, 1997	Apr CFTG
	AB	+	1GM	N20381	004	Jul 28, 1997	Mar CFTG
NICARDIPINE HYDROCHLORIDE							
INJECTABLE; INJECTION							
CARDENE							
	+	ESP PHARMA	2.5MG/ML	N19734	001	Jan 30, 1992	Mar CAHN
NITROFURANTOIN; NITROFURANTOIN, MACROCRYSTALLINE							
CAPSULE; ORAL							
NITROFURANTOIN (MONOHYDRATE/MACROCRYSTALS)							
	AB	EON	75MG;25MG	N77066	001	Apr 05, 2005	Mar NEWA
	AB	RANBAXY	75MG;25MG	N76951	001	Mar 30, 2005	Mar NEWA
NYSTATIN							
POWDER; TOPICAL							
NYSTATIN							
>A>	AT	UPSHER SMITH	100,000 UNITS/GM	N65183	001	May 03, 2005	Apr NEWA
OCTREOTIDE ACETATE							
INJECTABLE; INJECTION							
OCTREOTIDE ACETATE							
AP		BEDFORD	EQ 0.2MG BASE/ML	N76330	001	Apr 08, 2005	Mar NEWA
AP			EQ 1MG BASE/ML	N76330	002	Apr 08, 2005	Mar NEWA
OCTREOTIDE ACETATE (PRESERVATIVE FREE)							
AP		BEDFORD	EQ 0.05MG BASE/ML	N76313	001	Mar 28, 2005	Mar NEWA
AP			EQ 0.1MG BASE/ML	N76313	003	Mar 28, 2005	Mar NEWA
AP			EQ 0.5MG BASE/ML	N76313	002	Mar 28, 2005	Mar NEWA
SANDOSTATIN							
AP	+	NOVARTIS	EQ 0.05MG BASE/ML	N19667	001	Oct 21, 1988	Mar CFTG
AP	+		EQ 0.1MG BASE/ML	N19667	002	Oct 21, 1988	Mar CFTG
AP	+		EQ 0.2MG BASE/ML	N19667	004	Jun 12, 1991	Mar CFTG
AP	+		EQ 0.5MG BASE/ML	N19667	003	Oct 21, 1988	Mar CFTG
AP	+		EQ 1MG BASE/ML	N19667	005	Jun 12, 1991	Mar CFTG
OLSALAZINE SODIUM							
CAPSULE; ORAL							
DIPENTUM							
	+	UCB	250MG	N19715	001	Jul 31, 1990	Mar CAHN
OMEPRAZOLE							
CAPSULE, DELAYED REL PELLETS; ORAL							
PRILOSEC							
>D>		ASTRAZENECA	40MG	N19810	002	Jan 15, 1998	Apr CRLD
>A>	+		40MG	N19810	002	Jan 15, 1998	Apr CRLD
			40MG	N19810	002	Jan 15, 1998	Mar CTEG

OXALIPLATIN

INJECTABLE; IV (INFUSION)

ELOXATIN

+	SANOFI	50MG/VIAL	N21492 001	Aug 09, 2002	Mar	CRLD
+	SANOFI SYNTHELABO	50MG/10ML (5MG/ML)	N21759 001	Jan 31, 2005	Jan	NEWA
+		100MG/20ML (5MG/ML)	N21759 002	Jan 31, 2005	Jan	NEWA

OXAZEPAM

CAPSULE; ORAL

OXAZEPAM

>D>	AB	IVAX PHARMS	30MG	N70945 001	Aug 03, 1987	Apr	CRLD
>A>	AB	+	30MG	N70945 001	Aug 03, 1987	Apr	CRLD
>D>		SERAX					
>D>	AB	ALPHARMA US PHARMS	10MG	N15539 002		Apr	DISC
>A>		@	10MG	N15539 002		Apr	DISC
>D>	AB		15MG	N15539 004		Apr	DISC
>A>		@	15MG	N15539 004		Apr	DISC
>D>	AB	+	30MG	N15539 006		Apr	DISC
>A>		@	30MG	N15539 006		Apr	DISC

PACLITAXEL

FOR SUSPENSION; IV (INFUSION)

ABRAXANE

+	AM BIOSCIENCE	100MG/VIAL	N21660 001	Jan 07, 2005	Jan	NEWA
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PEMOLINE

TABLET, CHEWABLE; ORAL

PEMOLINE

AB	TEVA PHARMS	37.5MG	N75555 001	Feb 18, 2000	Mar	CAHN
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TABLET; ORAL

PEMOLINE

AB	TEVA PHARMS	18.75MG	N75030 003	Feb 22, 2000	Mar	CAHN
AB		37.5MG	N75030 001	Jan 29, 1999	Mar	CAHN
AB		75MG	N75030 002	Jan 29, 1999	Mar	CAHN

PENTOBARBITAL SODIUM

CAPSULE; ORAL

SODIUM PENTOBARBITAL

@	VALEANT PHARM INTL	100MG	N83264 001		Jan	DISC
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PHENDIMETRAZINE TARTRATE

TABLET; ORAL

BONTRIL PDM

AA	+	VALEANT	35MG	N85272 001		Feb	CRLD
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CAM-METRAZINE

@	ABC HOLDING	35MG	N83922 001		Feb	DISC
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@		35MG	N85318 001		Feb	DISC
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@		35MG	N85320 001		Feb	DISC
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@		35MG	N85321 001		Feb	DISC
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@		35MG	N85511 001		Feb	DISC
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@	CAMALL	35MG	N85756 001		Feb	DISC
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PHENDIMETRAZINE TARTRATE

@	ABC HOLDING	35MG	N85761 001		Feb	DISC
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@		35MG	N85941 001	Jun 27, 1983	Feb	DISC
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@	EON	35MG	N85830 001		Feb	DISC
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TABLET; ORAL

X-TROZINE

@ SHIRE RICHWOOD

35MG

N86553 001

Feb DISC

@

35MG

N86554 001

Feb DISC

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

ONA-MAST

@ MAST MM

30MG

N86511 001

Feb DISC

@

30MG

N86516 001

Feb DISC

PHENTERMINE HCL

@ ABC HOLDING

18.75MG

N88576 001 May 23, 1984 Feb DISC

@

30MG

N85417 001 Feb DISC

@

30MG

N86732 002 Feb DISC

@

30MG

N87215 001 Feb DISC

@

37.5MG

N87915 001 Dec 22, 1983 Feb DISC

@

37.5MG

N87918 001 Dec 22, 1983 Feb DISC

@

37.5MG

N87930 001 Oct 14, 1983 Feb DISC

@

37.5MG

N88610 001 Jun 04, 1984 Feb DISC

@

37.5MG

N88611 001 Jun 04, 1984 Feb DISC

@

37.5MG

N88625 001 Aug 23, 1984 Feb DISC

@ CAMALL

15MG

N86735 001 Feb DISC

@

30MG

N87226 001 Feb DISC

TABLET; ORAL

ONA MAST

@ MAST MM

8MG

N86260 001

Feb DISC

PHENTERMINE HCL

@ ABC HOLDING

8MG

N83923 001 Feb DISC

@

8MG

N85319 001 Feb DISC

@

37.5MG

N87805 001 Dec 06, 1982 Feb DISC

@

37.5MG

N88596 001 Apr 04, 1984 Feb DISC

AA

LANNETT

37.5MG

N40555 001 Apr 15, 2005 Mar NEWA

PHENTERMINE RESIN COMPLEX

CAPSULE, EXTENDED RELEASE; ORAL

IONAMIN

UCB

EQ 15MG BASE

N11613 004

Mar CAHN

+

EQ 30MG BASE

N11613 002

Mar CAHN

PHENYTOIN SODIUM

INJECTABLE; INJECTION

PHENYTOIN

AP

+

ELKINS SINN

50MG/ML

N84307 001

Mar CTEC

PHENYTOIN SODIUM

AP

HOSPIRA

50MG/ML

N89521 001 Mar 17, 1987 Mar CMFD

AP

50MG/ML

N89744 001 Dec 18, 1987 Mar CMFD

PIROXICAM

CAPSULE; ORAL

PIROXICAM

AB

TEVA PHARMS

10MG

N74103 001 Aug 28, 1992 Mar CAHN

AB

20MG

N74103 002 Aug 28, 1992 Mar CAHN

POTASSIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER

AP	HOSPIRA	14.9MG/ML	N20161 005	Nov 30, 1992	Mar	CMFD
AP		745MG/100ML	N20161 001	Nov 30, 1992	Mar	CMFD

POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER

AP	HOSPIRA	1.49GM/100ML	N20161 002	Nov 30, 1992	Mar	CMFD
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POTASSIUM CITRATE

TABLET, EXTENDED RELEASE; ORAL

UROCIT-K

MISSION PHARMA 5MEQ

N19071 001 Aug 30, 1985 Jan CTNA

+ 10MEQ

N19071 002 Aug 31, 1992 Jan CTNA

PRAMLINTIDE ACETATE

INJECTABLE; SUBCUTANEOUS

SYMLIN

+ AMYLIN EQ 3MG BASE/5ML (EQ 0.6MG BASE/ML)

N21332 001 Mar 16, 2005 Mar NEWA

PREDNISOLONE

SYRUP; ORAL

PREDNISOLONE

AA IVAX PHARMS 15MG/5ML

N40287 001 May 28, 1999 Jan CAHN

AA TEVA PHARMS 15MG/5ML

N40322 001 Jan 19, 2000 Mar CAHN

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION; ORAL

PEDIAPRED

AA + UCB EQ 5MG BASE/5ML

N19157 001 May 28, 1986 Mar CAHN

PREDNISOLONE SODIUM PHOSPHATE

>A> AA PHARM ASSOC EQ 15MG BASE/5ML

N76913 001 Apr 25, 2005 Apr NEWA

PRIMIDONE

TABLET; ORAL

MYSOLINE

>A> AB + VALEANT 50MG

N09170 003 Apr CAHN

>A> AB 250MG

N09170 002 Apr CAHN

>D> AB + XCEL PHARMS 50MG

N09170 003 Apr CAHN

>D> AB 250MG

N09170 002 Apr CAHN

PRIMIDONE

AB VINTAGE PHARMS 50MG

N40586 001 Feb 24, 2005 Feb NEWA

AB 250MG

N40586 002 Feb 24, 2005 Feb NEWA

PROCHLORPERAZINE MALEATE

TABLET; ORAL

PROCHLORPERAZINE MALEATE

AB TEVA PHARMS EQ 5MG BASE

N40120 001 Jul 11, 1996 Mar CAHN

AB EQ 10MG BASE

N40120 002 Jul 11, 1996 Mar CAHN

PROGESTERONE

INJECTABLE; INJECTION

PROGESTERONE

AO + WATSON LABS (UTAH) 50MG/ML

N17362 002 Feb CAHN

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL

PROMETHAZINE HCL

ABLE

12.5MG

N40558 001 Jul 01, 2004 Jan CTEC

PROPOFOL

INJECTABLE; INJECTION

PROPOFOL

AB BEDFORD

10MG/ML

N74848 001 Apr 19, 2005 Mar NEWA

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

INDERAL

>D> AB + WYETH PHARMS INC

10MG

N16418 001

Apr CRLD

>A> AB 10MG

N16418 001

Apr CRLD

QUINAPRIL HYDROCHLORIDE

TABLET; ORAL

QUINAPRIL HCL

AB EON

EQ 5MG BASE

N76803 001 Mar 02, 2005 Feb NEWA

AB EQ 10MG BASE

N76803 002 Mar 02, 2005 Feb NEWA

AB EQ 20MG BASE

N76803 003 Mar 02, 2005 Feb NEWA

AB EQ 40MG BASE

N76803 004 Mar 02, 2005 Feb NEWA

AB PAR PHARM EQ 5MG BASE

N76036 001 Jan 28, 2005 Jan NEWA

AB EQ 10MG BASE

N76036 002 Jan 28, 2005 Jan NEWA

AB EQ 20MG BASE

N76036 003 Jan 28, 2005 Jan NEWA

AB EQ 40MG BASE

N76036 004 Jan 28, 2005 Jan NEWA

QUINIDINE SULFATE

TABLET, EXTENDED RELEASE; ORAL

QUINIDINE SULFATE

+ TEVA PHARMS

300MG

N40045 001 Jun 30, 1994 Mar CAHN

RANITIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

RANITIDINE HCL

AP BEN VENUE

EQ 25MG BASE/ML

N74777 001 Mar 02, 2005 Feb NEWA

SODIUM BENZOATE; SODIUM PHENYLACETATE

SOLUTION; IV (INFUSION)

AMMONUL

+ UCYCLYD

10%;10% (5GM/50ML;5GM/50ML)

N20645 001 Feb 17, 2005 Feb NEWA

SODIUM CHLORIDE

SOLUTION; IRRIGATION

SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

AT HOSPIRA

450MG/100ML

N18380 001

Mar CMFD

SOMATREM

INJECTABLE; INJECTION

PROTROPIN

@ GENENTECH

5MG/VIAL

N19107 001 Oct 17, 1985 Mar DISC

@

10MG/VIAL

N19107 002 Oct 24, 1989 Mar DISC

SOMATROPIN RECOMBINANT

INJECTABLE; SUBCUTANEOUS

SEROSTIM LQ

SERONO

6MG/0.05VIAL

N20604 005 Feb 11, 2005 Feb NEWA

SULFAMETHOXAZOLE; TRIMETHOPRIM

TABLET; ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM

AB INTERPHARM

400MG;80MG

N76899 001 Jan 27, 2005 Jan NEWA

AB 800MG;160MG

N76899 002 Jan 27, 2005 Jan NEWA

TACROLIMUS

CAPSULE; ORAL

PROGRAF

+ FUJISAWA HLTHCARE

EQ 1MG BASE

N50708 001 Apr 08, 1994 Jan CRLD

TAMOXIFEN CITRATE

TABLET; ORAL

TAMOXIFEN CITRATE

@ PHARMACHEMIE

EQ 10MG BASE

N74539 001 Mar 31, 2003 Feb DISC

TELITHROMYCIN

TABLET; ORAL

KETEK

AVENTIS PHARMS

300MG

N21144 002 Feb 09, 2005 Feb NEWA

TERBUTALINE SULFATE

TABLET; ORAL

TERBUTALINE SULFATE

AB LANNETT

2.5MG

N77152 001 Mar 25, 2005 Mar NEWA

AB 5MG

N77152 002 Mar 25, 2005 Mar NEWA

TERCONAZOLE

CREAM; VAGINAL

TERCONAZOLE

AB ALTANA

0.4%

N76712 001 Feb 18, 2005 Jan NEWA

TESTOSTERONE CYPIONATE

INJECTABLE; INJECTION

TESTOSTERONE CYPIONATE

AO PADDOCK

200MG/ML

N40530 001 Jan 31, 2005 Jan NEWA

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL

SUMYCIN

@ APOTHECON

250MG

N60429 001

Mar DISC

@

500MG

N60429 003

Mar DISC

TETRACYCLINE HCL

AB + IVAX PHARMS

500MG

N60704 002

Mar CRLD

@ MAST MM

250MG

N62085 001

Feb DISC

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL

THEOPHYLLINE

>D> BC INWOOD LABS

125MG

N40052 002 Feb 14, 1994 Apr CTEC

		CAPSULE, EXTENDED RELEASE; ORAL							
		THEOPHYLLINE							
>A>		INWOOD LABS	125MG			N40052 002	Feb 14, 1994	Apr	CTEC
		<u>THIORIDAZINE HYDROCHLORIDE</u>							
		CONCENTRATE; ORAL							
		THIORIDAZINE HCL							
AA	+	TEVA PHARMS	30MG/ML			N89602 001	Nov 09, 1987	Mar	CAHN
AA	+		100MG/ML			N89603 001	Nov 09, 1987	Mar	CAHN
		<u>THIOTHIXENE HYDROCHLORIDE</u>							
		CONCENTRATE; ORAL							
		THIOTHIXENE HCL							
AA		TEVA PHARMS	EQ 5MG BASE/ML			N71554 001	Oct 16, 1987	Mar	CAHN
		<u>TOLTERODINE TARTRATE</u>							
		CAPSULE, EXTENDED RELEASE; ORAL							
		DETROL LA							
>D>	+	PHARMACIA AND UPJOHN	2MG			N21228 001	Dec 22, 2000	Apr	CRLD
>A>			2MG			N21228 001	Dec 22, 2000	Apr	CRLD
		<u>TOREMIFENE CITRATE</u>							
		TABLET; ORAL							
		FARESTON							
	+	GTX INC	EQ 60MG BASE			N20497 001	May 29, 1997	Jan	CAHN
		<u>TORSEMIDE</u>							
		TABLET; ORAL							
		TORSEMIDE							
AB		ROXANE	5MG			N76943 001	Mar 01, 2005	Feb	NEWA
AB			10MG			N76943 002	Mar 01, 2005	Feb	NEWA
AB			20MG			N76943 003	Mar 01, 2005	Feb	NEWA
		<u>TRETINOIN</u>							
		SOLUTION; TOPICAL							
		TRETINOIN							
AT		TEVA PHARMS	0.05%			N74873 001	Jun 19, 1998	Mar	CAHN
		<u>TRICHLORMETHIAZIDE</u>							
		TABLET; ORAL							
		NAQUA							
	@	SCHERING	4MG			N12265 002		Feb	DISC
		TRICHLORMETHIAZIDE							
	@	ABC HOLDING	4MG			N85568 001		Feb	DISC
	@	PAR PHARM	2MG			N87007 001		Feb	DISC
	@		4MG			N87005 001		Feb	DISC
		<u>TRIMETHOPRIM HYDROCHLORIDE</u>							
		SOLUTION; ORAL							
		PRIMSOL							
	@	TARO PHARMS NORTH	EQ 25MG BASE/5ML			N74374 001	Jun 23, 1995	Jan	CAHN
	+		EQ 50MG BASE/5ML			N74973 001	Jan 24, 2000	Jan	CAHN

URSODIOL

	CAPSULE; ORAL								
	URSODIOL								
AB	TEVA PHARMS	300MG		N75592 001	May 25, 2000	Mar	CAHN		

VALPROIC ACID

	SYRUP; ORAL								
	VALPROIC ACID								
AA	TEVA PHARMS	250MG/5ML		N73178 001	Aug 25, 1992	Mar	CAHN		

VERAPAMIL HYDROCHLORIDE

	CAPSULE, EXTENDED RELEASE; ORAL								
	VERELAN PM								
	ELAN PHARM	100MG		N20943 001	Nov 25, 1998	Mar	CRLD		
		200MG		N20943 002	Nov 25, 1998	Mar	CRLD		

VINORELBINE TARTRATE

	INJECTABLE; INJECTION								
	VINORELBINE TARTRATE								
AP	AM PHARM	EQ 10MG BASE/ML		N76849 001	Apr 18, 2005	Mar	NEWA		

PRESCRIPTION DRUG PRODUCT LIST - 25TH EDITION

OTC DRUG PRODUCT LIST - CUMULATIVE SUPPLMENT 4 - April 2005

2-1

ASPIRIN

TABLET; ORAL

BAYER EXTRA STRENGTH ASPIRIN FOR MIGRAINE PAIN

BAYER

500MG

N21317 001 Oct 18, 2001 Mar CMFD

BENTOQUATAM

LOTION; TOPICAL

IVY BLOCK

>D> + ENVIRODERM 5%

N20532 001 Aug 26, 1996 Apr CAHN

>A> + STAND HOMEOPATH 5%

N20532 001 Aug 26, 1996 Apr CAHN

CHLORHEXIDINE GLUCONATE

CLOTH; TOPICAL

CHLORHEXIDINE GLUCONATE

>A> + SAGE PRODS 2%

N21669 001 Apr 25, 2005 Apr NEWA

CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL

SPONGE; TOPICAL

CHLORAPREP ONE-STEP FREPP

>D> + MEDI FLEX HOSP 2%;70%

N20832 001 Jul 14, 2000 Apr CTNA

>A> + MEDI FLEX INC 2%;70%

N20832 001 Jul 14, 2000 Apr CTNA

CHLORAPREP WITH TINT

>A> + MEDI FLEX INC 2%;70%

N20832 002 May 03, 2005 Apr NEWA

CLOTRIMAZOLE

TABLET; VAGINAL

GYNIX

TEVA PHARMS

100MG

N73249 001 Feb 13, 1998 Mar CAHN

DEXTROMETHORPHAN POLISTIREX

SUSPENSION, EXTENDED RELEASE; ORAL

DELSYM

>D> + CELLTECH PHARMS EQ 30MG HBR/5ML

N18658 001 Oct 08, 1982 Apr CAHN

>A> + UCB EQ 30MG HBR/5ML

N18658 001 Oct 08, 1982 Apr CAHN

FAMOTIDINE

TABLET; ORAL

FAMOTIDINE

PERRIGO

10MG

N75400 001 Mar 18, 2005 Mar NEWA

WOCKHARDT

10MG

N77146 001 Mar 07, 2005 Feb NEWA

LOPERAMIDE HYDROCHLORIDE

SOLUTION; ORAL

IMODIUM A-D

>A> + MCNEIL 1MG/7.5ML

N19487 002 Jul 08, 2004 Apr NEWA

LORATADINE

SYRUP; ORAL

CLARITIN HIVES RELIEF

@ SCHERING

1MG/ML

N20641 003 Nov 19, 2003 Jan DISC

MICONAZOLE NITRATE

CREAM; VAGINAL

MICONAZOLE 3

TARO

4%

N76773 001 Mar 02, 2005 Feb NEWA

NICOTINE POLACRILEX

GUM, CHEWING; BUCCAL

NICOTINE POLACRILEX

>D>	WATSON LABS	EQ 2MG BASE	N76568 001	Jul 29, 2004	Apr	DISC
>A>	@	EQ 2MG BASE	N76568 001	Jul 29, 2004	Apr	DISC
>D>		EQ 2MG BASE	N76569 001	Jul 29, 2004	Apr	CTNA
>D>		EQ 4MG BASE	N76568 002	Jul 29, 2004	Apr	CTNA
>D>		EQ 4MG BASE	N76569 002	Jul 29, 2004	Apr	DISC
>A>	@	EQ 4MG BASE	N76569 002	Jul 29, 2004	Apr	DISC
>A>	NICOTINE POLACRILEX (MINT)					
>A>	WATSON LABS	EQ 2MG BASE	N76569 001	Jul 29, 2004	Apr	CTNA
>A>		EQ 4MG BASE	N76568 002	Jul 29, 2004	Apr	CTNA

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

CUMULATIVE SUPPLEMENT NUMBER 04 APRIL 2005

NO APRIL 2005 APPROVALS

ORPHAN PRODUCT DESIGNATIONS AND APPROVALS LIST

The list of List of Orphan Designations and Approvals is available at:

<http://www.fda.gov/orphan/designat/list.htm>

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

NO APRIL 2005 ADDITIONS

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY DATA

See report footnote for information regarding report content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>ALBUTEROL SULFATE - ALBUTEROL SULFATE HFA</u>					
021457 001	5605674	Feb 25, 2014	DP		
	5695743	Jul 06, 2010	DP	U-491	
	>A> 5766573	Nov 28, 2009		U-356	
	6352684	Nov 28, 2009	DP		
<u>ALPRAZOLAM - NIRAVAM</u>					
021726 001	6024981	Apr 09, 2018	DP		
	6221392	Apr 09, 2018	DP		
<u>ALPRAZOLAM - NIRAVAM</u>					
021726 002	6024981	Apr 09, 2018	DP		
	6221392	Apr 09, 2018	DP		
<u>ALPRAZOLAM - NIRAVAM</u>					
021726 003	6024981	Apr 09, 2018	DP		
	6221392	Apr 09, 2018	DP		
<u>ALPRAZOLAM - NIRAVAM</u>					
021726 004	6024981	Apr 09, 2018	DP		
	6221392	Apr 09, 2018	DP		
<u>ARIPIPRAZOLE - ABILIFY</u>					
021713 001				I-437	Sep 29, 2007
				I-401	Aug 28, 2006
				NCE	Nov 15, 2007
<u>ARSENIC TRIOXIDE - TRISENOX</u>					
021248 001	6855339	Nov 10, 2018	U-617		
	6861076	Nov 10, 2018	U-617		
<u>ATOMOXETINE HYDROCHLORIDE - STRATTERA</u>					
021411 007	5658590	Jan 11, 2015	U-494	NCE	Nov 26, 2007
	>A> 5658590*PED	Jul 11, 2015		PED	May 26, 2008
<u>ATOMOXETINE HYDROCHLORIDE - STRATTERA</u>					
021411 008	5658590	Jan 11, 2015	U-494	NCE	Nov 26, 2007
	>A> 5658590*PED	Jul 11, 2015		PED	May 26, 2008
<u>BEXAROTENE - TARGRETIN</u>					
021055 001	>A> 6043279	Apr 22, 2012	U-509		
	>A> 6320074	Apr 22, 2012	DS	U-509	
<u>BEXAROTENE - TARGRETIN</u>					
021056 001	>A> 6043279	Apr 22, 2012	U-510		
	>A> 6320074	Apr 22, 2012	DS	U-510	
<u>BORTEZOMIB - VELCADE</u>					
021602 001				I-452	Mar 25, 2008
<u>BROMFENAC SODIUM - XIBROM</u>					
021664 001				NP	Mar 24, 2008
<u>BUDESONIDE - ENTOCORT EC</u>					
021324 001				>A> I-454	Apr 29, 2008
<u>CANDESARTAN CILEXETIL - ATACAND</u>					
020838 001				I-448	Feb 22, 2008
<u>CANDESARTAN CILEXETIL - ATACAND</u>					
020838 002				I-448	Feb 22, 2008
<u>CANDESARTAN CILEXETIL - ATACAND</u>					
020838 003				I-448	Feb 22, 2008
<u>CANDESARTAN CILEXETIL - ATACAND</u>					
020838 004				I-448	Feb 22, 2008
<u>CARBAMAZEPINE - CARBATROL</u>					
020712 003	>A> 5326570	Jul 05, 2011	U-215		
	>A> 5912013	Jun 15, 2016	U-277		
<u>CARBAMAZEPINE - EQUETRO</u>					
021710 001	5326570	Jul 23, 2011	DP	U-627	
	5912013	Jun 15, 2016	DP		
<u>CARBAMAZEPINE - EQUETRO</u>					
021710 002	5326570	Jul 23, 2011	DP	U-627	
	5912013	Jun 15, 2016	DP		

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY DATA

See report footnote for information regarding report content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>CARBAMAZEPINE - EQUETRO</u>					
021710 003	5326570	Jul 23, 2011	DP	U-627	
	5912013	Jun 15, 2016	DP		
<u>CARBIDOPA; ENTACAPONE; LEVODOPA - STALEVO 100</u>					
021485 002	>A> 5446194	Oct 19, 2013	DS		
<u>CARBIDOPA; ENTACAPONE; LEVODOPA - STALEVO 150</u>					
021485 003	>A> 5446194	Oct 19, 2013	DS		
<u>CARBIDOPA; ENTACAPONE; LEVODOPA - STALEVO 50</u>					
021485 001	>A> 5446194	Oct 19, 2013	DS		
<u>CETRORELIX - CETROTIDE</u>					
021197 001	6863891	Feb 19, 2013		U-426	
<u>CETRORELIX - CETROTIDE</u>					
021197 002	6863891	Feb 19, 2013		U-426	
<u>CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - CHLORAPREP WITH TINT</u>					
020832 002				>A> NP	May 03, 2008
<u>CIPROFLOXACIN HYDROCHLORIDE; HYDROCORTISONE - CIPRO HC</u>					
020805 001	>A> 4844902	Feb 11, 2008	DP		
	>A> 5843930	Jul 06, 2015		U-646	
<u>CLOFARABINE - CLOLAR</u>					
021673 001	4918179	Jun 14, 2005	DS		
	5384310	May 23, 2009	DS	DP	
	5661136	Aug 26, 2014		U-626	
<u>COLESTIPOL HYDROCHLORIDE - COLESTID</u>					
020222 001	5490987	Feb 13, 2013	DP		
<u>DAPTOMYCIN - CUBICIN</u>					
021572 001	6852689	Sep 24, 2019		U-282	
<u>DAPTOMYCIN - CUBICIN</u>					
021572 002	6852689	Sep 24, 2019		U-282	
<u>DARIFENACIN HYDROBROMIDE - ENABLEX</u>					
021513 001	5096890	Mar 13, 2010	DS	DP	U-631
	6106864	Aug 21, 2016		DP	U-630
<u>DARIFENACIN HYDROBROMIDE - ENABLEX</u>					
021513 002	5096890	Mar 13, 2010	DS	DP	U-631
	6106864	Aug 21, 2016		DP	U-630
<u>DESIRUDIN RECOMBINANT - IPRIVASK</u>					
021271 001				NCE	Apr 04, 2008
<u>DESLOMATADINE - CLARINEX</u>					
021165 001	>A> 4659716	Apr 21, 2006		U-427	
	>A> 4659716*PED	Oct 21, 2006		U-427	
<u>DESLOMATADINE - CLARINEX</u>					
021300 001	>A> 4659716	Apr 21, 2006	DP	U-611	
	>A> 4659716*PED	Oct 21, 2006			
<u>DESLOMATADINE - CLARINEX</u>					
021312 001	>A> 4659716	Apr 21, 2006		U-427	
	>A> 4659716*PED	Oct 21, 2006		U-427	
<u>DESLOMATADINE; PSEUDOEPHEDRINE SULFATE - CLARINEX D 24 HOUR</u>					
021605 001	>A> 4659716	Apr 21, 2006	DP	U-644	NCE
	>A> 4659716*PED	Oct 21, 2006			NC
	>A> 6100274	Jul 07, 2019	DP		PED
	>A> 6100274*PED	Jan 07, 2020			
<u>DEXRAZOXANE HYDROCHLORIDE - DEXRAZOXANE</u>					
076068 001				PC	Aug 27, 2005
<u>DEXRAZOXANE HYDROCHLORIDE - DEXRAZOXANE</u>					
076068 002				>A> PC	Oct 19, 2005
<u>DEXTROMETHORPHAN POLISTIREX - DELSYM</u>					
018658 001	>A> 5980882	Apr 16, 2017	DP		
<u>DIVALPROEX SODIUM - DEPAKOTE ER</u>					
021168 001	6720004	Dec 18, 2018	DP		

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY DATA

See report footnote for information regarding report content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>DIVALPROEX SODIUM - DEPAKOTE ER</u>					
021168 002	6720004	Dec 18, 2018	DP		
<u>DOXAZOSIN MESYLATE - CARDURA XL</u>					
021269 001				NDF	Feb 22, 2008
<u>DOXAZOSIN MESYLATE - CARDURA XL</u>					
021269 002	4837111	Mar 21, 2008	DP	NDF	Feb 22, 2008
<u>ENTACAPONE - COMTAN</u>					
020796 001	>A> 5446194	Oct 19, 2013	DS		
<u>ENTECAVIR - BARACLUDE</u>					
021797 001	>A> 5206244	Oct 18, 2010	DS	>A> NCE	Mar 29, 2010
<u>ENTECAVIR - BARACLUDE</u>					
021797 002	>A> 5206244	Oct 18, 2010	DS	>A> NCE	Mar 29, 2010
<u>ENTECAVIR - BARACLUDE</u>					
021798 001	>A> 5206244	Oct 18, 2010	DS	>A> NCE	Mar 29, 2010
<u>EPINEPHRINE; LIDOCAINE HYDROCHLORIDE - LIDOSITE TOPICAL SYSTEM KIT</u>					
021504 001	6862473	Sep 30, 2013	DP		
<u>EPLERENONE - INSPRA</u>					
021437 001	4559332	Apr 09, 2006	DS DP	U-537	
<u>EPLERENONE - INSPRA</u>					
021437 002	4559332	Apr 09, 2006	DS DP	U-537	
<u>EPLERENONE - INSPRA</u>					
021437 003	4559332	Apr 09, 2006	DS DP	U-537	
<u>ERTAPENEM SODIUM - INVANZ</u>					
021337 001	5478820	Feb 02, 2013		NCE	Nov 21, 2006
	5478820*PED	Aug 02, 2013		PED	May 21, 2007
	5652233	Feb 02, 2013			
	5652233*PED	Aug 02, 2013			
	5952323	May 15, 2017			
	5952323*PED	Nov 15, 2017			
<u>ESMOLOL HYDROCHLORIDE - ESMOLOL HCL</u>					
076323 001				PC	May 01, 2005
<u>ESOMEPRAZOLE MAGNESIUM - NEXIUM</u>					
021153 001	4738974	Apr 19, 2006	DS DP	U-635	
	4738974	Apr 19, 2006	DS DP	U-373	
	4738974*PED	Oct 19, 2006		U-373	
	6875872	May 27, 2014	DS		
	6875872*PED	Nov 27, 2014			
<u>ESOMEPRAZOLE MAGNESIUM - NEXIUM</u>					
021153 002	4738974	Apr 19, 2006	DS DP	U-635	
	4738974	Apr 19, 2006	DS DP	U-373	
	4738974*PED	Oct 19, 2006		U-373	
	6875872	May 27, 2014	DS		
	6875872*PED	Nov 27, 2014			
<u>ESOMEPRAZOLE SODIUM - NEXIUM IV</u>					
021689 001	>A> 5877192	May 27, 2014		U-643	>A> NE
	>A> 5877192*PED	Nov 27, 2014			>A> NDF
	>A> 6143771	May 27, 2014	DP	U-643	
<u>ESOMEPRAZOLE SODIUM - NEXIUM IV</u>					
021689 002	>A> 5877192	May 27, 2014		U-643	>A> NE
	>A> 5877192*PED	Nov 27, 2014			>A> NDF
	>A> 6143771	May 27, 2014	DP	U-643	
<u>ESTROGENS, CONJUGATED SYNTHETIC B - ENJUVIA</u>					
021443 001	6660726	Mar 08, 2021	DS DP	U-284	NP
	6660726	Mar 08, 2021	DS DP	U-196	
	6855703	Feb 12, 2021	DS DP	U-284	
<u>ESTROGENS, CONJUGATED SYNTHETIC B - ENJUVIA</u>					
021443 002	6660726	Mar 08, 2021	DS DP	U-284	NP
	6660726	Mar 08, 2021	DS DP	U-196	
	6855703	Feb 12, 2021	DS DP	U-284	

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<u>ESTROGENS, CONJUGATED SYNTHETIC B - ENJUVIA</u>					
021443 003	6660726	Mar 08, 2021	DS DP	U-284	
	6660726	Mar 08, 2021	DS DP	U-196	
	6855703	Feb 12, 2021	DS DP	U-284	
<u>ESTROGENS, CONJUGATED SYNTHETIC B - ENJUVIA</u>					
021443 004	6660726	Mar 08, 2021	DS DP	U-284	
	6660726	Mar 08, 2021	DS DP	U-196	
	6855703	Feb 12, 2021	DS DP	U-284	
<u>ESZOPICLONE - LUNESTA</u>					
021476 001	6319926	Jan 16, 2012		U-620	
	6444673	Jan 16, 2012	DS DP		
	6864257	Aug 30, 2012		U-629	
<u>ESZOPICLONE - LUNESTA</u>					
021476 002	6319926	Jan 16, 2012		U-620	
	6444673	Jan 16, 2012	DS DP		
	6864257	Aug 30, 2012		U-629	
<u>ESZOPICLONE - LUNESTA</u>					
021476 003	6319926	Jan 16, 2012		U-620	
	6444673	Jan 16, 2012	DS DP		
	6864257	Aug 30, 2012		U-629	
<u>EXENATIDE SYNTHETIC - BYETTA</u>					
021773 001				>A> NCE	Apr 28, 2010
<u>EXENATIDE SYNTHETIC - BYETTA</u>					
021773 002				>A> NCE	Apr 28, 2010
<u>FAMOTIDINE - FLUXID</u>					
021712 001	6024981	Apr 09, 2018	DP		
	6221392	Apr 09, 2018	DP		
<u>FAMOTIDINE - FLUXID</u>					
021712 002	6024981	Apr 09, 2018	DP		
	6221392	Apr 09, 2018	DP		
<u>FENTANYL - DURAGESIC-12</u>					
019813 005				NPP PED	May 20, 2006 Nov 20, 2006
<u>FENTANYL CITRATE - ACTIQ</u>					
020747 001	5785989	May 01, 2005			
<u>FENTANYL CITRATE - ACTIQ</u>					
020747 002	5785989	May 01, 2005			
<u>FENTANYL CITRATE - ACTIQ</u>					
020747 003	5785989	May 01, 2005			
<u>FENTANYL CITRATE - ACTIQ</u>					
020747 004	5785989	May 01, 2005			
<u>FENTANYL CITRATE - ACTIQ</u>					
020747 005	5785989	May 01, 2005			
<u>FENTANYL CITRATE - ACTIQ</u>					
020747 006	5785989	May 01, 2005			
<u>FLUOCINOLONE ACETONIDE - RETISERT</u>					
021737 001				>A> NDF	Apr 08, 2008
<u>FLUOCINONIDE - VANOS</u>					
021758 001				NP	Feb 11, 2008
<u>FLUTICASONE PROPIONATE - CUTIVATE</u>					
021152 001				NDF PED	Mar 31, 2008 Sep 30, 2008
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 100/50</u>					
021077 001	6536427	Mar 01, 2011	DP		
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 250/50</u>					
021077 002	6536427	Mar 01, 2011	DP		
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 500/50</u>					
021077 003	6536427	Mar 01, 2011	DP		
<u>GALANTAMINE HYDROBROMIDE - REMINYL</u>					
021169 001	6358527	Jun 06, 2017	DP	U-322	

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<u>GALANTAMINE HYDROBROMIDE - REMINYL</u>					
021169 002	6358527	Jun 06, 2017	DP U-322		
<u>GALANTAMINE HYDROBROMIDE - REMINYL</u>					
021169 003	6358527	Jun 06, 2017	DP U-322		
<u>GEMCITABINE HYDROCHLORIDE - GEMZAR</u>					
020509 001	4808614	May 15, 2010	DS	I-428	May 19, 2007
	4808614*PED	Nov 15, 2010		>A> M-40	Apr 26, 2008
	5464826	Nov 07, 2012		>A> PED	Oct 26, 2008
	5464826*PED	May 07, 2013		PED	Nov 19, 2007
<u>GEMCITABINE HYDROCHLORIDE - GEMZAR</u>					
020509 002	4808614	May 15, 2010	DS	I-428	May 19, 2007
	4808614*PED	Nov 15, 2010		>A> M-40	Apr 26, 2008
	5464826	Nov 07, 2012		>A> PED	Oct 26, 2008
	5464826*PED	May 07, 2013		PED	Nov 19, 2007
<u>GRANISETRON HYDROCHLORIDE - KYTRIL</u>					
020239 003	4886808	Dec 29, 2007	DS DP U-89	I-369	Aug 16, 2005
<u>GRANISETRON HYDROCHLORIDE - KYTRIL</u>					
020239 004				I-369	Aug 16, 2005
<u>HYDROCHLOROTHIAZIDE; IRBESARTAN - AVALIDE</u>					
020758 004	>A> 5270317	Sep 30, 2011	DS DP		
	>A> 5270317*PED	Mar 30, 2012			
	>A> 5994348	Jun 07, 2015	DP		
	>A> 5994348*PED	Dec 07, 2015			
<u>HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM - HYZAAR</u>					
020387 001	>A> 5138069	Aug 11, 2009	DS		
<u>HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM - HYZAAR</u>					
020387 002	>A> 5138069	Aug 11, 2009	DS		
<u>HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL - BENICAR HCT</u>					
021532 002	>A> 6878703	Nov 19, 2021		U-3	
<u>HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL - BENICAR HCT</u>					
021532 003	>A> 6878703	Nov 19, 2021		U-3	
<u>HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL - BENICAR HCT</u>					
021532 005	>A> 6878703	Nov 19, 2021		U-3	
<u>IBANDRONATE SODIUM - BONIVA</u>					
021455 002	>A> 4927814	Jul 09, 2007	DS DP U-642	D-96	Mar 24, 2008
	>A> 6294196	Oct 07, 2019	DP	NS	Mar 24, 2008
				NCE	May 16, 2008
<u>IMATINIB MESYLATE - GLEEVEC</u>					
021335 001	5521184	Jan 04, 2015			
<u>IMATINIB MESYLATE - GLEEVEC</u>					
021335 002	5521184	Jan 04, 2015			
<u>IMATINIB MESYLATE - GLEEVEC</u>					
021588 001	5521184	Jan 04, 2015			
<u>IMATINIB MESYLATE - GLEEVEC</u>					
021588 002	5521184	Jan 04, 2015			
<u>ITRACONAZOLE - ITRACONAZOLE</u>					
076104 001				PC	Aug 08, 2005
<u>LETROZOLE - FEMARA</u>					
020726 001				I-446	Oct 29, 2007
<u>LEUPROLIDE ACETATE - ELIGARD</u>					
021731 001	4938763	Oct 03, 2008	DP	U-621	
	5278201	Jan 11, 2011	DP		
	5324519	Jun 28, 2011	DP		
	5599552	Feb 04, 2014	DP	U-621	
	5739176	Oct 03, 2008	DP	U-621	
	6395293	Sep 28, 2013	DP		
	6565874	Oct 28, 2018	DP	U-621	
	6626870	Mar 27, 2020	DP		
	6773714	Oct 28, 2018		U-621	
	RE37950	Oct 03, 2008	DP	U-621	

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<u>LEVABUTEROL TARTRATE - XOPENEX HFA</u>					
021730 001	>A> 5225183	Jul 06, 2010	DP	NP	Mar 11, 2008
	>A> 5362755	Nov 08, 2011		U-636	
	>A> 5439670	Jul 06, 2010	DP		
	>A> 5547994	Aug 20, 2013		U-636	
	>A> 5605674	Feb 25, 2014	DP		
	>A> 5695743	Jul 06, 2010	DP	U-636	
	>A> 5760090	Jan 05, 2010		U-636	
	>A> 5836299	Nov 17, 2017	DP		
	>A> 5844002	Jan 05, 2010		U-636	
	>A> 6083993	Jan 05, 2010		U-636	
	>A> 6352684	Nov 28, 2009	DP		
<u>LINEZOLID - ZYVOX</u>					
021130 001	5688792	Nov 18, 2014	DS	U-319	I-431 Jun 23, 2007
	5688792*PED	May 18, 2015			I-402 Jul 22, 2006
	6514529	Mar 15, 2021		DP	NPP Dec 19, 2005
	6514529*PED	Sep 15, 2021			NCE Apr 18, 2005
	6559305	Jan 29, 2021	DS		PED Dec 23, 2007
	6559305*PED	Jul 29, 2021			PED Jan 22, 2007
					PED Jun 19, 2006
					PED Oct 18, 2005
<u>LINEZOLID - ZYVOX</u>					
021130 002	5688792	Nov 18, 2014	DS	U-319	I-431 Jun 23, 2007
	5688792*PED	May 18, 2015			I-402 Jul 22, 2006
	6514529	Mar 15, 2021		DP	NPP Dec 19, 2005
	6514529*PED	Sep 15, 2021			NCE Apr 18, 2005
	6559305	Jan 29, 2021	DS		PED Dec 23, 2007
	6559305*PED	Jul 29, 2021			PED Jan 22, 2007
					PED Jun 19, 2006
					PED Oct 18, 2005
<u>LINEZOLID - ZYVOX</u>					
021131 001	5688792	Nov 18, 2014		U-319	I-431 Jun 23, 2007
	5688792*PED	May 18, 2015			I-402 Jul 22, 2006
	6559305	Jan 29, 2021	DS		NPP Dec 19, 2005
	6559305*PED	Jul 29, 2021			NCE Apr 18, 2005
					PED Dec 23, 2007
					PED Jan 22, 2007
					PED Jun 19, 2006
					PED Oct 18, 2005
<u>LINEZOLID - ZYVOX</u>					
021132 001	5688792	Nov 18, 2014	DS	U-319	I-431 Jun 23, 2007
	5688792*PED	May 18, 2015			I-402 Jul 22, 2006
	6559305	Jan 29, 2021	DS		NPP Dec 19, 2005
	6559305*PED	Jul 29, 2021			NCE Apr 18, 2005
					PED Dec 23, 2007
					PED Jan 22, 2007
					PED Jun 19, 2006
					PED Oct 18, 2005
<u>LOVASTATIN - ALTOPREV</u>					
021316 001	6485748	Dec 12, 2017	DP		
<u>LOVASTATIN - ALTOPREV</u>					
021316 002	6485748	Dec 12, 2017	DP		
<u>LOVASTATIN - ALTOPREV</u>					
021316 003	6485748	Dec 12, 2017	DP		
<u>LOVASTATIN - ALTOPREV</u>					
021316 004	6485748	Dec 12, 2017	DP		
<u>MEDROXYPROGESTERONE ACETATE - DEPO-SUBQ PROVERA 104</u>					
021583 001	6495534	May 15, 2020	DP	I-451	Mar 25, 2008
<u>MELOXICAM - MOBIC</u>					
020938 001				I-430	Jul 16, 2007
				NCE	Apr 13, 2005
				PED	Jan 16, 2008
				PED	Oct 13, 2005

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MELOXICAM - MOBIC					
021530 001	6184220	Mar 25, 2019	DP	I-430	Jul 16, 2007
	6184220*PED	Sep 25, 2019		NCE	Apr 13, 2005
				PED	Jan 16, 2008
				PED	Oct 13, 2005
METFORMIN HYDROCHLORIDE - FORTAMET					
021574 001	6866866	Mar 17, 2021	DP		
METFORMIN HYDROCHLORIDE - FORTAMET					
021574 002	6866866	Mar 17, 2021	DP		
METFORMIN HYDROCHLORIDE - METFORMIN HCL					
076863 001				PC	Apr 12, 2005
METOPROLOL SUCCINATE - TOPROL-XL					
019962 001	4927640	May 22, 2007	DP	D-95	Feb 15, 2008
	4957745	Sep 18, 2007	DP		
	5001161	Sep 18, 2007	DP		
	5081154	Sep 18, 2007	DS		
METOPROLOL SUCCINATE - TOPROL-XL					
019962 002	4927640	May 22, 2007	DP	D-95	Feb 15, 2008
	4957745	Sep 18, 2007	DP		
	5001161	Sep 18, 2007	DP		
	5081154	Sep 18, 2007	DS		
METOPROLOL SUCCINATE - TOPROL-XL					
019962 003	4927640	May 22, 2007	DP	D-95	Feb 15, 2008
	4957745	Sep 18, 2007	DP		
	5001161	Sep 18, 2007	DP		
	5081154	Sep 18, 2007	DS		
METOPROLOL SUCCINATE - TOPROL-XL					
019962 004	4927640	May 22, 2007	DP	D-95	Feb 15, 2008
	4957745	Sep 18, 2007	DP		
	5001161	Sep 18, 2007	DP		
	5081154	Sep 18, 2007	DS		
MICAFUNGIN SODIUM - MYCAMINE					
021506 002				NCE	Mar 16, 2010
MODAFINIL - PROVIGIL					
020717 001				I-449	Jan 23, 2007
MODAFINIL - PROVIGIL					
020717 002				I-449	Jan 23, 2007
MOMETASONE FUROATE - ASMANEX TWISTHALER					
021067 001	>A> 5394868	Jun 25, 2012	DP	NP	Mar 30, 2008
	>A> 5687710	Nov 18, 2014	DP		
	>A> 5829434	Nov 03, 2015	DP		
	>A> 5889015	Jan 27, 2014			
	>A> 6057307	Jan 27, 2014	DP		
	>A> 6240918	Feb 20, 2017	DP		
	>A> 6365581	Jan 27, 2014			
	>A> 6503537	Mar 17, 2018	DP		
	>A> 6677322	Jan 27, 2014			
MOMETASONE FUROATE MONOHYDRATE - NASONEX					
020762 001	5837699	Jan 27, 2014	DP	U-625	
	6127353	Oct 03, 2017	DS		
	6723713	Jan 27, 2014			
NATEGLINIDE - STARLIX					
021204 001	6844008	Nov 14, 2017	DP	U-214	
	RE34878	Sep 08, 2009			
NATEGLINIDE - STARLIX					
021204 002	6844008	Nov 14, 2017	DP	U-214	
	RE34878	Sep 08, 2009			
OCTREOTIDE ACETATE - OCTREOTIDE ACETATE (PRESERVATIVE FREE)					
076313 001				>A> PC	Oct 02, 2005
OCTREOTIDE ACETATE - OCTREOTIDE ACETATE (PRESERVATIVE FREE)					
076313 002				>A> PC	Oct 02, 2005

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<u>OCTREOTIDE ACETATE - OCTREOTIDE ACETATE (PRESERVATIVE FREE)</u>					
076313 003				>A> PC	Oct 02, 2005
<u>OCTREOTIDE ACETATE - SANDOSTATIN</u>					
019667 005	5753618	Jul 08, 2008			
<u>OLMESARTAN MEDOXOMIL - BENICAR</u>					
021286 001	>A> 6878703	Nov 19, 2021	U-3		
<u>OLMESARTAN MEDOXOMIL - BENICAR</u>					
021286 003	>A> 6878703	Nov 19, 2021	U-3		
<u>OLMESARTAN MEDOXOMIL - BENICAR</u>					
021286 004	>A> 6878703	Nov 19, 2021	U-3		
<u>OMEPRAZOLE - ZEGERID</u>					
021706 001	5840737	Jul 16, 2016	DS	U-624	
	5840737	Jul 16, 2016	DS	U-623	
	6489346	Jul 16, 2016	DS DP	U-624	
	6489346	Jul 16, 2016	DS DP	U-623	
	6645988	Jul 16, 2016	DS DP		
	6699885	Jul 16, 2016		U-624	
	6699885	Jul 16, 2016		U-623	
	6780882	Jul 16, 2016	DS DP		
<u>ONDANSETRON HYDROCHLORIDE - ZOFTRAN</u>					
020007 001				>A> D-98	Mar 25, 2008
				D-97	Mar 25, 2008
				>A> PED	Sep 25, 2008
				PED	Sep 25, 2008
<u>ONDANSETRON HYDROCHLORIDE - ZOFTRAN PRESERVATIVE FREE</u>					
020007 003				>A> D-98	Mar 25, 2008
				D-97	Mar 25, 2008
				>A> PED	Sep 25, 2008
				PED	Sep 25, 2008
<u>OXALIPLATIN - ELOXATIN</u>					
021759 001				I-441	Nov 04, 2007
				NCE	Aug 09, 2007
<u>OXALIPLATIN - ELOXATIN</u>					
021759 002				I-441	Nov 04, 2007
				NCE	Aug 09, 2007
<u>OXCARBAZEPINE - TRILEPTAL</u>					
021014 001				NCE	Jan 14, 2005
				PED	Jul 14, 2005
<u>OXCARBAZEPINE - TRILEPTAL</u>					
021014 002				NCE	Jan 14, 2005
				PED	Jul 14, 2005
<u>OXCARBAZEPINE - TRILEPTAL</u>					
021014 003				NCE	Jan 14, 2005
				PED	Jul 14, 2005
<u>OXCARBAZEPINE - TRILEPTAL</u>					
021285 001				NCE	Jan 14, 2005
				PED	Jul 14, 2005
<u>PACLITAXEL - ABRAXANE</u>					
021660 001	5439686	Feb 22, 2013	DP	NP	Jan 07, 2008
	5498421	Mar 12, 2013	DP	U-634	
	6096331	Feb 22, 2013	DP	U-633	
	6506405	Feb 22, 2013	DP	U-633	
	6537579	Feb 22, 2013		U-632	
	6749868	Feb 22, 2013	DP		
	6753006	Feb 22, 2013	DP		
<u>PEGAPTANIB SODIUM - MACUGEN</u>					
021756 001	5919455	Oct 27, 2013	DS		
	5932462	Aug 03, 2016	DS		
	6011020	Jan 04, 2017	DS		
	6051698	Sep 17, 2012	DS		
	6113906	Oct 27, 2013	DS		
	6147204	Jun 11, 2010	DS		
	6426335	Jun 11, 2010		U-622	

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<u>PRAMLINTIDE ACETATE - SYMLIN</u>					
021332 001	>A> 5175145	Dec 29, 2009		NCE	Mar 16, 2010
	>A> 5686411	Nov 11, 2014	DS DP	U-638	
	>A> 5814600	Sep 29, 2015		U-639	
	>A> 5998367	Mar 08, 2011	DS DP		
	>A> 6114304	Sep 05, 2017		U-640	
	>A> 6410511	Jan 09, 2018	DP		
	>A> 6608029	Sep 07, 2013		U-641	
	>A> 6610824	Mar 08, 2011	DS		
<u>PREGABALIN - LYRICA</u>					
021446 001	6001876	Jul 16, 2017		U-55	
	6197819	Mar 06, 2018	DS DP		
<u>PREGABALIN - LYRICA</u>					
021446 002	6001876	Jul 16, 2017		U-55	
	6197819	Mar 06, 2018	DS DP		
<u>PREGABALIN - LYRICA</u>					
021446 003	6001876	Jul 16, 2017		U-55	
	6197819	Mar 06, 2018	DS DP		
<u>PREGABALIN - LYRICA</u>					
021446 004	6001876	Jul 16, 2017		U-55	
	6197819	Mar 06, 2018	DS DP		
<u>PREGABALIN - LYRICA</u>					
021446 005	6001876	Jul 16, 2017		U-55	
	6197819	Mar 06, 2018	DS DP		
<u>PREGABALIN - LYRICA</u>					
021446 006	6001876	Jul 16, 2017		U-55	
	6197819	Mar 06, 2018	DS DP		
<u>PREGABALIN - LYRICA</u>					
021446 007	6001876	Jul 16, 2017		U-55	
	6197819	Mar 06, 2018	DS DP		
<u>PREGABALIN - LYRICA</u>					
021446 008	6001876	Jul 16, 2017		U-55	
	6197819	Mar 06, 2018	DS DP		
<u>RIBAVIRIN - COPEGUS</u>					
021511 001				I-447	Feb 25, 2008
<u>RISPERIDONE - RISPERDAL</u>					
021444 004	>A> 4804663	Dec 29, 2007	DS DP	U-543	
	>A> 5648093	Jul 15, 2014		DP	
	>A> 6224905	Jun 10, 2017		DP	
<u>RISPERIDONE - RISPERDAL</u>					
021444 005	>A> 4804663	Dec 29, 2007	DS DP	U-543	
	>A> 5648093	Jul 15, 2014		DP	
	>A> 6224905	Jun 10, 2017		DP	
<u>ROSIGLITAZONE MALEATE - AVANDIA</u>					
021071 002	5002953	Aug 30, 2008	DS DP	U-628	I-453
	5002953	Aug 30, 2008	DS DP	U-329	
	5741803	Apr 21, 2015	DS DP	U-628	
	5741803	Apr 21, 2015	DS DP	U-329	
<u>ROSIGLITAZONE MALEATE - AVANDIA</u>					
021071 003	5002953	Aug 30, 2008	DS DP	U-628	I-453
	5002953	Aug 30, 2008	DS DP	U-329	
	5741803	Apr 21, 2015	DS DP	U-628	
	5741803	Apr 21, 2015	DS DP	U-329	
<u>ROSIGLITAZONE MALEATE - AVANDIA</u>					
021071 004	5002953	Aug 30, 2008	DS DP	U-628	I-453
	5002953	Aug 30, 2008	DS DP	U-329	
	5741803	Apr 21, 2015	DS DP	U-628	
	5741803	Apr 21, 2015	DS DP	U-329	
<u>ROSUVASTATIN CALCIUM - CRESTOR</u>					
021366 002	6858618	Dec 17, 2021		U-618	
<u>ROSUVASTATIN CALCIUM - CRESTOR</u>					
021366 003	6858618	Dec 17, 2021		U-618	

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<u>ROSUVASTATIN CALCIUM - CRESTOR</u>					
021366 004	6858618	Dec 17, 2021	U-618		
<u>ROSUVASTATIN CALCIUM - CRESTOR</u>					
021366 005	6858618	Dec 17, 2021	U-618		
<u>SIROLIMUS - RAPAMUNE</u>					
021083 001	>A> 5536729	Sep 30, 2013	DP	>A> NPP >A> PED	Mar 11, 2008 Sep 11, 2008
<u>SIROLIMUS - RAPAMUNE</u>					
021110 001	>A> 5989591	Mar 11, 2018	DP	>A> NPP >A> PED	Mar 11, 2008 Sep 11, 2008
<u>SIROLIMUS - RAPAMUNE</u>					
021110 002	>A> 5989591	Mar 11, 2018	DP	>A> NPP >A> PED	Mar 11, 2008 Sep 11, 2008
<u>SIROLIMUS - RAPAMUNE</u>					
021110 003	>A> 5100899	Jun 06, 2009	U-290	>A> NPP	Mar 11, 2008
	>A> 5100899*PED	Dec 06, 2009		>A> PED	Sep 11, 2008
	>A> 5212155	May 18, 2010	U-291		
	>A> 5212155*PED	Nov 18, 2010			
	>A> 5403833	Apr 04, 2012	U-293		
	>A> 5403833*PED	Oct 04, 2012			
	>A> 5989591	Mar 11, 2018	DP		
	>A> 5989591*PED	Sep 11, 2018			
<u>SODIUM BENZOATE; SODIUM PHENYLACETATE - AMMONUL</u>					
020645 001				NDF ODE	Feb 17, 2008 Feb 17, 2012
<u>SOMATROPIN RECOMBINANT - GENOTROPIN PRESERVATIVE FREE</u>					
020280 001	>A> 4968299	Jun 28, 2008	DP		
	6152897	Nov 20, 2018	DP		
<u>SOMATROPIN RECOMBINANT - GENOTROPIN PRESERVATIVE FREE</u>					
020280 002	>A> 4968299	Jun 28, 2008	DP		
	6152897	Nov 20, 2018	DP		
<u>SOMATROPIN RECOMBINANT - GENOTROPIN PRESERVATIVE FREE</u>					
020280 003	>A> 4968299	Jun 28, 2008	DP		
	6152897	Nov 20, 2018	DP		
<u>SOMATROPIN RECOMBINANT - GENOTROPIN PRESERVATIVE FREE</u>					
020280 005	>A> 4968299	Jun 28, 2008	DP		
	6152897	Nov 20, 2018	DP		
<u>SOMATROPIN RECOMBINANT - GENOTROPIN PRESERVATIVE FREE</u>					
020280 008	>A> 4968299	Jun 28, 2008	DP		
	6152897	Nov 20, 2018	DP		
<u>SOMATROPIN RECOMBINANT - GENOTROPIN PRESERVATIVE FREE</u>					
020280 009	>A> 4968299	Jun 28, 2008	DP		
	6152897	Nov 20, 2018	DP		
<u>SOMATROPIN RECOMBINANT - GENOTROPIN PRESERVATIVE FREE</u>					
020280 010	>A> 4968299	Jun 28, 2008	DP		
<u>SOMATROPIN RECOMBINANT - GENOTROPIN PRESERVATIVE FREE</u>					
020280 011	>A> 4968299	Jun 28, 2008	DP		
<u>SOMATROPIN RECOMBINANT - GENOTROPIN PRESERVATIVE FREE</u>					
020280 012	>A> 4968299	Jun 28, 2008	DP		
<u>SOMATROPIN RECOMBINANT - GENOTROPIN PRESERVATIVE FREE</u>					
020280 013	>A> 4968299	Jun 28, 2008	DP		
<u>TELITHROMYCIN - KETEK</u>					
021144 002	>A> 5635485	Apr 21, 2015	DS DP	U-578	NCE
	>A> D459798	Sep 24, 2015	DP		Apr 01, 2009
<u>TEMOZOLOMIDE - TEMODAR</u>					
021029 001	5260291	Aug 11, 2013	DS DP	U-619	I-450
	5260291*PED	Feb 11, 2014			ODE
<u>TEMOZOLOMIDE - TEMODAR</u>					
021029 002	5260291	Aug 11, 2013	DS DP	U-619	I-450
	5260291*PED	Feb 11, 2014			ODE

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY DATA

See report footnote for information regarding report content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE			PATENT CODES			EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE	
<u>TEMOZOLOMIDE - TEMODAR</u>										
021029 003	5260291 5260291*PED	Aug 11, 2013 Feb 11, 2014	DS	DP	U-619		I-450 ODE	Mar 15, 2008 Mar 15, 2012		
<u>TEMOZOLOMIDE - TEMODAR</u>										
021029 004	5260291 5260291*PED	Aug 11, 2013 Feb 11, 2014	DS	DP	U-619		I-450 ODE	Mar 15, 2008 Mar 15, 2012		
<u>THALIDOMIDE - THALOMID</u>										
020785 001	>A> 6869399	Oct 23, 2020			U-371					
<u>THALIDOMIDE - THALOMID</u>										
020785 002	>A> 6869399	Oct 23, 2020			U-371					
<u>THALIDOMIDE - THALOMID</u>										
020785 003	>A> 6869399	Oct 23, 2020			U-371					
<u>TOPIRAMATE - TOPAMAX</u>										
020505 001							I-41	Aug 11, 2007		
<u>TOPIRAMATE - TOPAMAX</u>										
020505 002							I-41	Aug 11, 2007		
<u>TOPIRAMATE - TOPAMAX</u>										
020505 003							I-41	Aug 11, 2007		
<u>TOPIRAMATE - TOPAMAX</u>										
020505 004							I-41	Aug 11, 2007		
<u>TOPIRAMATE - TOPAMAX</u>										
020505 005							I-41	Aug 11, 2007		
<u>TOPIRAMATE - TOPAMAX</u>										
020505 006							I-41	Aug 11, 2007		
<u>TOPIRAMATE - TOPAMAX SPRINKLE</u>										
020844 001							I-41	Aug 11, 2007		
<u>TOPIRAMATE - TOPAMAX SPRINKLE</u>										
020844 002							I-41	Aug 11, 2007		
<u>TOPIRAMATE - TOPAMAX SPRINKLE</u>										
020844 003							I-41	Aug 11, 2007		
<u>VORICONAZOLE - VFEND</u>										
021266 001	5567817	May 24, 2016	DS	DP	U-540					
<u>VORICONAZOLE - VFEND</u>										
021266 002	5567817	May 24, 2016	DS	DP	U-540					
<u>VORICONAZOLE - VFEND</u>										
021267 001	5567817	May 24, 2016	DS	DP	U-540					
<u>VORICONAZOLE - VFEND</u>										
021630 001	5567817	May 24, 2016	DS	DP	U-540					
<u>ZICONOTIDE - PRIALT</u>										
021060 001	5364842 5364842 5795864 5859186 5859186	Dec 30, 2011 Dec 30, 2011 Jun 27, 2015 Dec 30, 2011 Dec 30, 2011				U-55 U-48 DP U-55 U-48				
<u>ZICONOTIDE - PRIALT</u>										
021060 002	5364842 5364842 5795864 5859186 5859186	Dec 30, 2011 Dec 30, 2011 Jun 27, 2015 Dec 30, 2011 Dec 30, 2011				U-55 U-48 DP U-55 U-48				
<u>ZICONOTIDE - PRIALT</u>										
021060 003	5364842 5364842 5795864 5859186 5859186	Dec 30, 2011 Dec 30, 2011 Jun 27, 2015 Dec 30, 2011 Dec 30, 2011				U-55 U-48 DP U-55 U-48				

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY DATA

See report footnote for information regarding report content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>ZICONOTIDE - PRIALT</u>					
021060 004	5364842	Dec 30, 2011		U-55	
	5364842	Dec 30, 2011		U-48	
	5795864	Jun 27, 2015	DP		
	5859186	Dec 30, 2011		U-55	
	5859186	Dec 30, 2011		U-48	

Footnote:

1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).

2. Patents submitted on FDA Form 3542 and listed after August 18, 2003 will have one to three patent codes indicating specific patent claims as submitted by the sponsor:

DS = Drug Substance claim

DP = Drug Product claim

U and number = Method of Use claim (may be multiple). Specific Method of use claims are listed at

<http://www.fda.gov/cder/orange/patex.htm>

3. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. They may not be flagged with respect to other claims which may apply.

4. *PED and PED represent pediatric exclusivity. Patents with pediatric exclusivity granted after August 18, 2003 will be indicated with *PED as was done prior to August 18, 2003. Patents with *PED added after August 18, 2003 will not contain any information relative to the patent itself other than the *PED extension. Information related specifically to the patent will be conveyed on the original patent only.

PATENT AND EXCLUSIVITY TERMS

Due to space limitations in the patent and exclusivity columns, abbreviations and references have been developed. Refer to the APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 25th Edition for a full listing of patent and exclusivity terms (Abbreviations, Dosing Schedule, Indications, and Patent Use Codes).

The current complete list of Patent terms is available at <http://www.accessdata.fda.gov/scripts/cder/ob/docs/pattermsall.cfm>