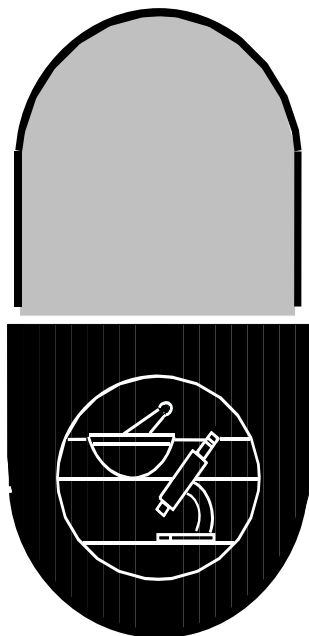


**CUMULATIVE  
SUPPLEMENT 04  
April 2008**



**APPROVED  
DRUG PRODUCTS**

**WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**28<sup>th</sup> EDITION**

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

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

**APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**28<sup>th</sup> EDITION**

**Cumulative Supplement 04**

**April 2008**

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**APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**28<sup>th</sup> EDITION**

**CUMULATIVE SUPPLEMENT 04  
April 2008**

**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, 28th 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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 27th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 28th 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 CUMULATIVE SUPPLEMENT CONTENT

Since February 2005, we have been providing daily Electronic Orange Book (EOB) product information for new generic drug approvals. Daily generic updates provide the consumer with the current list of approved generic products which is important for substitution purposes. Previously, a first-time-generic product approved early in the month would not be published in the Cumulative Supplement (CS) for several weeks.

The CS monthly update publish goal is by the end of the following month's second work week (e.g., November's supplement will be updated by the end of the second full work week in December).

Currently, the monthly PDF CS includes:

- Generic product ANDA (Abbreviated New Drug Approval) approvals as of the date of publication.
- All product changes received and processed as of the date of publication.
  - Refer to CS Section 1.8 Cumulative Supplement Legend for types of changes
  - Discontinued products will be processed as of the date of publication. There will be circumstances where a product is discontinued in one month, however, it will be reported in a different month's CS. For example, the Orange Book Staff received a letter November 7 that the product has been discontinued from manufacturing and marketing. The Orange Book subsequently publishes the October CS on November 14. The product will show in the October CS that it is discontinued even though the date of discontinuance is the day that the Orange Book Staff receives notification (November 7).

- New Drug Application (NDA) approvals (20,000 and 50,000 series) appear in the CS month they were approved.
- Patent information, also updated daily in the EOB, is current to the date of publication.
- Exclusivity information is updated monthly and current to the date of publication.

Every effort is made to ensure the Cumulative Supplement is current and accurate. Applicant holders are requested to inform the FDA Orange Book Staff (OBS) of any changes or corrections. The OBS can be contacted by email at [drugproducts@cder.fda.gov](mailto:drugproducts@cder.fda.gov). Send Changes by FAX: 240-276-8974; mail to:

FDA/CDER Orange Book Staff  
Office of Generic Drugs, HFD-610  
7500 Standish Place  
Rockville, MD 20855-2773

### 1.3 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.

<u>FORMER APPLICANT NAME</u> <u>(FORMER ABBREVIATED NAME)</u>	<u>NEW APPLICANT NAME</u> <u>(NEW ABBREVIATED NAME)</u>
BRISTOL MYERS SQUIBB MEDICAL IMAGING (BRISTOL MYERS)	LANTHEUS MEDICAL IMAGING INC (LANTHEUS MEDCL)
CIS US INC (CIS)	PHARMALUCENCE INC (PHARMALUCENCE)
CONNETICS CORP (CONNECTICS)	STIEFEL LABORATORIES INC (STIEFEL LABS INC)
RELIANT PHARMACEUTICALS LLC (RELIANT PHARMS)	SMITHKLINE BBECHAM CORP DBA GLAXOSMITHKLINE (SMITHKLINE BEECHAM)

### 1.4 AVAILABILITY OF THE EDITION

Since 1997, the Electronic Orange Book Query (EOBQ) <http://www.fda.gov/cder/ob/default.htm>, has been available on the

internet and has become the updated-every-month Orange Book. 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.

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

The downloaded Annual Edition and Cumulative Supplements are also available in a paper version (Approved Drug Products with Therapeutic Equivalence Evaluations, ADP) from the U.S. Government Printing Office: <http://www.bookstore.gpo.gov/>; toll free 866-512-1800.

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 provided in eobzip.exe and eobzip.zip format. The files are updated concurrently with the monthly cumulative supplements. The annual Orange Book Edition Appendices A, B, and C in PDF format 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>.

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

### DESCRIPTION OF REPORT

This report provides summary counts derived from the product information in the Prescription Drug Product List and the current Cumulative Supplement. Products included in the counts are domestically marketed drug products approved for both safety and effectiveness under section 505 of the Federal Food, Drug, and Cosmetic Act. Excluded are approved drug products marketed by distributors; those marketed solely abroad; and those now regarded as medical devices, biologics or foods.

The baseline column (Dec 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 2007</u>	<u>MAR 2008</u>	<u>JUN 2007</u>	<u>SEPT 2007</u>
DRUG PRODUCTS LISTED	12302	12459	11900	12130
SINGLE SOURCE	2489 (20.2%)	2514 (20.2%)	2483 (20.9%)	2494 (20.6%)
MULTISOURCE	9724 (79.0%)	9856 (79.1%)	9328 (78.4%)	9547 (78.7%)
THERAPEUTICALLY EQUIVALENT	9571 (77.8%)	9703 (77.9%)	9148 (76.9%)	9394 (77.4%)
NOT THERAPEUTICALLY EQUIVALENT	153 (1.2%)	153 (1.2%)	180 (1.5%)	153 (1.3%)
EXCEPTIONS <sup>1</sup>	89 (0.7%)	89 (0.7%)	89 (0.7%)	89 (0.7%)
NEW MOLECULAR ENTITIES APPROVED	7	7	7	10
NUMBER OF APPLICANTS	693	710	679	683

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

**1.6 CUMULATIVE SUPPLEMENT LEGEND**

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

The individual product record contains the Therapeutic Equivalence Code, Reference Listed Drug symbol, applicant holder, strength(s), New Drug 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.

PRESCRIPTION DRUG PRODUCT LIST - 28TH EDITION

RX DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2008

1-1

ACARBOSE

TABLET; ORAL

>A>		ACARBOSE						
>A>	AB	COBALT LABS INC	25MG	N77532	001	May 07, 2008	Apr	NEWA
>A>	AB		50MG	N77532	002	May 07, 2008	Apr	NEWA
>A>	AB		100MG	N77532	003	May 07, 2008	Apr	NEWA
>A>	AB	ROXANE	25MG	N78470	001	May 07, 2008	Apr	NEWA
>A>	AB		50MG	N78470	002	May 07, 2008	Apr	NEWA
>A>	AB		100MG	N78470	003	May 07, 2008	Apr	NEWA

PRECOSE

>D>		BAYER PHARMS	25MG	N20482	004	May 29, 1997	Apr	CFTG
>A>	AB		25MG	N20482	004	May 29, 1997	Apr	CFTG
>D>			50MG	N20482	001	Sep 06, 1995	Apr	CFTG
>A>	AB		50MG	N20482	001	Sep 06, 1995	Apr	CFTG
>D>			100MG	N20482	002	Sep 06, 1995	Apr	CFTG
>A>	AB		100MG	N20482	002	Sep 06, 1995	Apr	CFTG

ACEBUTOLOL HYDROCHLORIDE

CAPSULE; ORAL

ACEBUTOLOL HYDROCHLORIDE

AB		AMNEAL PHARM	EQ 200MG BASE	N75047	001	Dec 30, 1999	Feb	CAHN
AB			EQ 400MG BASE	N75047	002	Dec 30, 1999	Feb	CAHN

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

@ MUTUAL PHARM 300MG;15MG

N89671 001 Feb 10, 1988 Feb DISC

ACETAMINOPHEN; HYDROCODONE BITARTRATE

SOLUTION; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

@ MIKART 500MG/15ML;5MG/15ML

N89557 001 Apr 29, 1992 Feb DISC

>A>	+	PHARM ASSOC	325MG/15ML;10MG/15ML	N40834	001	Apr 18, 2008	Apr	NEWA
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ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

TABLET; ORAL

PERCOCET

AA	+	ENDO PHARMS	325MG;5MG	N40330	002	Jun 25, 1999	Feb	CRLD
		@	325MG;5MG	N85106	002		Feb	DISC

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL

PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

AB		CONCORD LABS NJ	650MG;100MG	N77821	001	Feb 11, 2008	Jan	NEWA
----	--	-----------------	-------------	--------	-----	--------------	-----	------

ACETOHEXAMIDE

TABLET; ORAL

ACETOHEXAMIDE

@ BARR 250MG

N70869 001 Feb 09, 1987 Feb DISC

@ 500MG

N70870 001 Feb 09, 1987 Jan DISC

WATSON LABS 250MG

N71893 001 Nov 25, 1987 Feb CTEC

+ 500MG

N71894 001 Nov 25, 1987 Jan CRLD

ACYCLOVIR

CAPSULE; ORAL

ACYCLOVIR

@ APOTHECON 200MG N74889 001 Oct 31, 1997 Feb DISC

TABLET; ORAL

ACYCLOVIR

@ APOTHECON 400MG N74891 001 Oct 31, 1997 Feb DISC

@ 800MG N74891 002 Oct 31, 1997 Feb DISC

ALBUTEROL SULFATE

SYRUP; ORAL

ALBUTEROL SULFATE

@ ACTAVIS MID ATLANTIC EQ 2MG BASE/5ML N75262 001 Mar 30, 1999 Feb DISC

TABLET; ORAL

ALBUTEROL SULFATE

@ WATSON LABS EQ 4MG BASE N72630 001 Jan 31, 1991 Feb DISC

ALBUTEROL SULFATE; IPRATROPIUM BROMIDE

SOLUTION; INHALATION

ALBUTEROL SULFATE AND IPRATROPIUM BROMIDE

&gt;D&gt; AN BREATH LTD EQ 0.083% BASE;0.017% N77063 001 Dec 31, 2007 Apr CAHN

&gt;A&gt; AN COBALT LABS INC EQ 0.083% BASE;0.017% N77063 001 Dec 31, 2007 Apr CAHN

ALENDRONATE SODIUM

TABLET; ORAL

ALENDRONATE SODIUM

AB BARR EQ 70MG BASE N76184 001 Feb 06, 2008 Jan NEWA

AB TEVA PHARMS EQ 5MG BASE N75710 001 Feb 06, 2008 Jan NEWA

AB EQ 10MG BASE N75710 002 Feb 06, 2008 Jan NEWA

AB EQ 35MG BASE N75710 003 Feb 06, 2008 Jan NEWA

AB EQ 40MG BASE N75710 004 Feb 06, 2008 Jan NEWA

AB EQ 70MG BASE N75710 005 Feb 06, 2008 Jan NEWA

FOSAMAX

AB MERCK AND CO INC EQ 5MG BASE N20560 003 Apr 25, 1997 Jan CFTG

AB EQ 10MG BASE N20560 001 Sep 29, 1995 Jan CFTG

AB EQ 35MG BASE N20560 004 Oct 20, 2000 Jan CFTG

AB EQ 40MG BASE N20560 002 Sep 29, 1995 Jan CFTG

AB + EQ 70MG BASE N20560 005 Oct 20, 2000 Jan CFTG

ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

TEKTURNA HCT

NOVARTIS EQ 150MG BASE;12.5MG N22107 001 Jan 18, 2008 Jan NEWA

EQ 150MG BASE;25MG N22107 002 Jan 18, 2008 Jan NEWA

EQ 300MG BASE;12.5MG N22107 003 Jan 18, 2008 Jan NEWA

+ EQ 300MG BASE;25MG N22107 004 Jan 18, 2008 Jan NEWA

ALOSETRON HYDROCHLORIDE

TABLET; ORAL

LOTRONEX

PROMETHEUS LABS EQ 0.5MG BASE N21107 002 Dec 23, 2003 Mar CAHN

+ EQ 1MG BASE N21107 001 Feb 09, 2000 Mar CAHN

ALPRAZOLAM

TABLET; ORAL

ALPRAZOLAM

@	TEVA	0.25MG	N74085 001	Feb 16, 1994	Feb	DISC
@		0.5MG	N74085 002	Feb 16, 1994	Feb	DISC
@		1MG	N74085 003	Feb 16, 1994	Feb	DISC
@		2MG	N74085 004	Feb 26, 1996	Feb	DISC

AMANTADINE HYDROCHLORIDE

SYRUP; ORAL

AMANTADINE HYDROCHLORIDE

@	TEVA PHARMS	50MG/5ML	N73115 001	Aug 23, 1991	Feb	DISC
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AMIFOSTINE

INJECTABLE; INJECTION

AMIFOSTINE

AP	SUN PHARM INDS	500MG/VIAL	N77126 001	Mar 14, 2008	Mar	NEWA
AP	+ MEDIMMUNE ONCOLOGY	500MG/VIAL	N20221 001	Dec 08, 1995	Mar	CFTG

AMIODARONE HYDROCHLORIDE

INJECTABLE; INJECTION

AMIODARONE HYDROCHLORIDE

>D>	AP	+ BEN VENUE	50MG/ML	N76088 001	Oct 15, 2002	Apr	DISC
>A>		@	50MG/ML	N76088 001	Oct 15, 2002	Apr	DISC
AP		HIKMA FARMACEUTICA	50MG/ML	N77234 001	Feb 25, 2008	Feb	NEWA

TABLET; ORAL

AMIODARONE HYDROCHLORIDE

@	TEVA	200MG	N74895 001	Apr 16, 1999	Feb	DISC
---	------	-------	------------	--------------	-----	------

AMLODIPINE BESYLATE

TABLET; ORAL

AMLODIPINE BESYLATE

@	GENPHARM	EQ 2.5MG BASE	N77362 001	Jul 09, 2007	Feb	DISC
@		EQ 5MG BASE	N77362 002	Jul 09, 2007	Feb	DISC
@		EQ 10MG BASE	N77362 003	Jul 09, 2007	Feb	DISC
AB	INTERPHARM	EQ 2.5MG BASE	N78477 001	Jan 16, 2008	Jan	NEWA
AB		EQ 5MG BASE	N78477 002	Jan 16, 2008	Jan	NEWA
AB		EQ 10MG BASE	N78477 003	Jan 16, 2008	Jan	NEWA
AB	MATRIX LABS LTD	EQ 2.5MG BASE	N78224 001	Feb 27, 2008	Feb	NEWA
AB		EQ 5MG BASE	N78224 002	Feb 27, 2008	Feb	NEWA
AB		EQ 10MG BASE	N78224 003	Feb 27, 2008	Feb	NEWA
AB	MUTUAL PHARMA	EQ 2.5MG BASE	N78081 001	Jan 31, 2008	Jan	NEWA
AB		EQ 5MG BASE	N78081 002	Jan 31, 2008	Jan	NEWA
AB		EQ 10MG BASE	N78081 003	Jan 31, 2008	Jan	NEWA

AMOXICILLIN

TABLET, EXTENDED RELEASE; ORAL

MOXATAG

+	MIDDLEBROOK PHARMS	775MG	N50813 001	Jan 23, 2008	Jan	NEWA
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ARIPIPIRAZOLE

TABLET, ORALLY DISINTEGRATING; ORAL

ABILIFY

>D>		OTSUKA	20MG	N21729 004	Jun 07, 2006	Apr	DISC
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TABLET, ORALLY DISINTEGRATING; ORAL

## ABILIFY

>A>	@ OTSUKA	20MG	N21729 004	Jun 07, 2006	Apr	DISC
>D>		30MG	N21729 005	Jun 07, 2006	Apr	DISC
>A>	@	30MG	N21729 005	Jun 07, 2006	Apr	DISC

ATENOLOL

## INJECTABLE; INJECTION

## TENORMIN

	@ ASTRAZENECA	0.5MG/ML	N19058 001	Sep 13, 1989	Feb	DISC
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## TABLET; ORAL

## ATENOLOL

	@ PLIVA	25MG	N74101 001	Jul 17, 1997	Feb	DISC
	@	50MG	N74101 002	Jul 17, 1997	Feb	DISC
	@	100MG	N74101 003	Jul 17, 1997	Feb	DISC
	@ SANDOZ	25MG	N74265 001	Feb 28, 1994	Feb	DISC
	@	50MG	N74265 002	Feb 28, 1994	Feb	DISC
	@	100MG	N74265 003	Feb 28, 1994	Feb	DISC
	@ SCS	50MG	N73676 001	Oct 30, 1992	Feb	DISC
	@	100MG	N73676 002	Oct 30, 1992	Feb	DISC

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

## TABLET; ORAL

## DIPHENOXYLATE HYDROCHLORIDE W/ ATROPINE SULFATE

>D>	@ LEINER	0.025MG; 2.5MG	N85766 001		Apr	CAHN
>A>	@ PVT FORM	0.025MG; 2.5MG	N85766 001		Apr	CAHN

ATROPINE SULFATE; EDROPHONIUM CHLORIDE

## INJECTABLE; INJECTION

## ENLON-PLUS

	@ BAXTER HLTHCARE CORP	0.14MG/ML; 10MG/ML	N19677 001	Nov 06, 1991	Feb	DISC
	@	0.14MG/ML; 10MG/ML	N19678 001	Nov 06, 1991	Feb	DISC

AZITHROMYCIN

## TABLET; ORAL

## AZITHROMYCIN

AB	WOCKHARDT	EQ 250MG BASE	N65404 001	Feb 11, 2008	Jan	NEWA
AB		EQ 500MG BASE	N65405 001	Feb 11, 2008	Jan	NEWA
AB		EQ 600MG BASE	N65302 003	Feb 11, 2008	Jan	NEWA

AZTREONAM

## INJECTABLE; INJECTION

## AZACTAM

	@ BRISTOL MYERS SQUIBB	500MG/VIAL	N50580 001	Dec 31, 1986	Jan	DISC
--	------------------------	------------	------------	--------------	-----	------

BENDAMUSTINE HYDROCHLORIDE

## POWDER; IV (INFUSION)

## TREANDA

	+ CEPHALON	100MG/VIAL	N22249 001	Mar 20, 2008	Mar	NEWA
--	------------	------------	------------	--------------	-----	------

BENDROFLUMETHIAZIDE; NADOLOL

## TABLET; ORAL

## NADOLOL AND BENDROFLUMETHAZIDE

AB	MYLAN	5MG; 40MG	N78688 001	Feb 15, 2008	Feb	NEWA
AB		5MG; 80MG	N78688 002	Feb 15, 2008	Feb	NEWA

BENZONATATE

CAPSULE; ORAL

BENZONATATE

AA	ORIT LABS LLC	100MG	N40682 001	Jul 30, 2007	Jan	CAHN
AA		200MG	N40682 002	Jul 30, 2007	Jan	CAHN
AA	SUN PHARM INDS INC	100MG	N40587 001	Mar 19, 2008	Mar	NEWA
AA		200MG	N40587 002	Mar 19, 2008	Mar	NEWA

BENZTHIAZIDE

TABLET; ORAL

BENZTHIAZIDE

>D>	@ LEINER	50MG	N83206 001		Apr	CAHN
>A>	@ PVT FORM	50MG	N83206 001		Apr	CAHN

BENZTROPINE MESYLATE

TABLET; ORAL

BENZTROPINE MESYLATE

AA	ACTAVIS TOTOWA	0.5MG	N40699 001	Feb 14, 2008	Jan	NEWA
AA		1MG	N40705 001	Feb 14, 2008	Jan	NEWA
AA		2MG	N40706 001	Feb 14, 2008	Jan	NEWA
	@ MUTUAL PHARM	1MG	N81264 001	Jan 23, 1992	Feb	DISC
	@	2MG	N81265 001	Jan 23, 1992	Feb	DISC

BETHANECHOL CHLORIDE

TABLET; ORAL

BETHANECHOL CHLORIDE

AA	LANNETT	5MG	N40703 001	Mar 27, 2008	Mar	NEWA
AA		10MG	N40704 001	Mar 27, 2008	Mar	NEWA
AA		25MG	N40678 003	Mar 27, 2008	Mar	NEWA
AA		50MG	N40677 001	Mar 27, 2008	Mar	NEWA

BLEOMYCIN SULFATE

INJECTABLE; INJECTION

BLEOMYCIN SULFATE

AP	ABRAXIS PHARM	EQ 15 UNITS BASE/VIAL	N65185 001	Jan 28, 2008	Jan	NEWA
AP		EQ 30 UNITS BASE/VIAL	N65185 002	Jan 28, 2008	Jan	NEWA
AP	BEDFORD	EQ 15 UNITS BASE/VIAL	N65042 002	Oct 17, 2001	Jan	CTNA
AP		EQ 30 UNITS BASE/VIAL	N65042 001	Oct 17, 2001	Jan	CTNA
AP	HOSPIRA	EQ 15 UNITS BASE/VIAL	N65031 001	Mar 10, 2000	Jan	CTNA
AP		EQ 30 UNITS BASE/VIAL	N65031 002	Mar 10, 2000	Jan	CTNA
AP	PHARMACHEMIE BV	EQ 15 UNITS BASE/VIAL	N65201 001	Dec 13, 2007	Jan	CTNA
AP	TEVA PARENTERAL	EQ 15 UNITS BASE/VIAL	N65033 001	Jun 27, 2000	Jan	CTNA
AP		EQ 30 UNITS BASE/VIAL	N65033 002	Jun 27, 2000	Jan	CTNA

BRIMONIDINE TARTRATE

SOLUTION/DROPS; OPHTHALMIC

BRIMONIDINE TARTRATE

AT	SANDOZ	0.2%	N78075 001	Jan 30, 2008	Jan	NEWA
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BROMODIPHENHYDRAMINE HYDROCHLORIDE; CODEINE PHOSPHATE

SYRUP; ORAL

BROMODIPHENHYDRAMINE HYDROCHLORIDE AND CODEINE PHOSPHATE

	@ MORTON GROVE	12.5MG/5ML;10MG/5ML	N88626 001	Oct 12, 1984	Feb	DISC
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BUMETANIDE

INJECTABLE; INJECTION

BUMETANIDE

>A>	AP	BAXTER HLTHCARE	0.25MG/ML	N79196 001	Apr 30, 2008	Apr	NEWA
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BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE

INJECTABLE; INJECTION

BUPIVACAINE HYDROCHLORIDE AND EPINEPHRINE

>D>		HOSPIRA	0.5%;0.005MG/ML	N71169 001	Jun 16, 1988	Apr	DISC
>A>		@	0.5%;0.005MG/ML	N71169 001	Jun 16, 1988	Apr	DISC
>D>		+	0.75%;0.005MG/ML	N71171 001	Jun 16, 1988	Apr	DISC
>A>		@	0.75%;0.005MG/ML	N71171 001	Jun 16, 1988	Apr	DISC

BUPROPION HYDROBROMIDE

>A>		TABLET, EXTENDED RELEASE; ORAL					
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>A>		APLENZIN					
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>A>		+	BIOVAIL LABS INTL	174MG	N22108 001	Apr 23, 2008	Apr	NEWA
>A>				348MG	N22108 002	Apr 23, 2008	Apr	NEWA
>A>				522MG	N22108 003	Apr 23, 2008	Apr	NEWA

BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

BUPROPION HYDROCHLORIDE

AB1		ACTAVIS	150MG	N77455 002	Mar 12, 2008	Mar	NEWA
AB2			150MG	N77475 001	Mar 12, 2008	Mar	CTEC
AB1			150MG	N77475 001	Mar 12, 2008	Feb	NEWA

CABERGOLINE

TABLET; ORAL

CABERGOLINE

>A>	AB	COBALT LABS INC	0.5MG	N78035 001	Apr 21, 2008	Apr	NEWA	
>D>	AB	PAR PHARM	0.5MG	N76310 001	Dec 29, 2005	Apr	CRLD	
>A>	AB	+	0.5MG	N76310 001	Dec 29, 2005	Apr	CRLD	
>D>		DOSTINEX						
>D>	AB	+	PHARMACIA AND UPJOHN	0.5MG	N20664 001	Dec 23, 1996	Apr	DISC
>A>		@	0.5MG	N20664 001	Dec 23, 1996	Apr	DISC	

CAFFEINE CITRATE

SOLUTION; ORAL

CAFFEINE CITRATE

AA		ABRAXIS PHARM PRODS	EQ 30MG BASE/3ML (EQ 10MG BASE/ML)	N78002 001	Jan 31, 2008	Jan	NEWA
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CALCIPOTRIENE

SOLUTION; TOPICAL

CALCIPOTRIENE

>A>								
>A>	AT		NYCOMED US	0.005%	N78305 001	May 06, 2008	Apr	NEWA
>D>			DOVONEX					
>D>		+	LEO PHARM	0.005%	N20611 001	Mar 03, 1997	Apr	CFTG
>A>	AT	+		0.005%	N20611 001	Mar 03, 1997	Apr	CFTG

CALCITRIOL

INJECTABLE; INJECTION

CALCITRIOL

AP		AKORN	0.001MG/ML	N78066 001	Jan 29, 2008	Jan	NEWA
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## INJECTABLE; INJECTION

## CALCITRIOL

AP	AKORN	0.002MG/ML	N78066 002	Jan 29, 2008	Jan	NEWA
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CALCIUM ACETATE

## CAPSULE; ORAL

## CALCIUM ACETATE

AB	ROXANE	EQ 169MG CALCIUM	N77728 001	Feb 26, 2008	Feb	NEWA
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## PHOSLO GELCAPS

AB	+ FRESENIUS MEDCL	EQ 169MG CALCIUM	N21160 003	Apr 02, 2001	Feb	CFTG
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## TABLET; ORAL

## CALCIUM ACETATE

>D>	+ ROXANE	EQ 169MG CALCIUM	N77693 001	Jan 30, 2008	Apr	DISC
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>A>	@	EQ 169MG CALCIUM	N77693 001	Jan 30, 2008	Apr	DISC
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	+	EQ 169MG CALCIUM	N77693 001	Jan 30, 2008	Jan	NEWA
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CAPTOPRIL

## TABLET; ORAL

## CAPTOPRIL

## @ SANDOZ

		12.5MG	N74481 001	Feb 13, 1996	Feb	DISC
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	@	12.5MG	N74519 001	Feb 13, 1996	Feb	DISC
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	@	25MG	N74481 002	Feb 13, 1996	Feb	DISC
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	@	25MG	N74519 002	Feb 13, 1996	Feb	DISC
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	@	50MG	N74481 003	Feb 13, 1996	Feb	DISC
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	@	50MG	N74519 003	Feb 13, 1996	Feb	DISC
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	@	100MG	N74481 004	Feb 13, 1996	Feb	DISC
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	@	100MG	N74519 004	Feb 13, 1996	Feb	DISC
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	@ WATSON LABS	12.5MG	N74576 001	Apr 23, 1996	Feb	DISC
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	@	25MG	N74576 002	Apr 23, 1996	Feb	DISC
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	@	50MG	N74576 003	Apr 23, 1996	Feb	DISC
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	@	100MG	N74576 004	Apr 23, 1996	Feb	DISC
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CARBINOXAMINE MALEATE

## SOLUTION; ORAL

## CARBINOXAMINE MALEATE

AA	BOCA PHARMA	4MG/5ML	N40814 001	Feb 26, 2008	Feb	NEWA
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AA	+ MIKART	4MG/5ML	N40458 001	Apr 25, 2003	Feb	CTEC
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CARBOPLATIN

## INJECTABLE; IV (INFUSION)

## CARBOPLATIN

>A>	AP	EBEWE PHARMA	EQ 50MG/5ML(10MG/ML)	N78280 001	May 08, 2008	Apr	NEWA
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>A>	AP		EQ 150MG/15ML(10MG/ML)	N78280 002	May 08, 2008	Apr	NEWA
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>A>	AP		EQ 450MG/45ML(10MG/ML)	N78280 003	May 08, 2008	Apr	NEWA
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CEFADROXIL/CEFADROXIL HEMIHYDRATE

## CAPSULE; ORAL

## CEFADROXIL

AB	HIKMA	EQ 500MG BASE	N65311 001	Feb 07, 2006	Jan	CAHN
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## FOR SUSPENSION; ORAL

## CEFADROXIL

AB	LUPIN	EQ 250MG BASE/5ML	N65396 001	Feb 21, 2008	Feb	NEWA
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AB		EQ 500MG BASE/5ML	N65396 002	Feb 21, 2008	Feb	NEWA
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CEFAZOLIN SODIUM

INJECTABLE; INJECTION

KEFZOL

AP	ACS DOBFAR	EQ 500MG BASE/VIAL	N61773 002		Mar	CMFD
AP		EQ 1GM BASE/VIAL	N61773 003		Mar	CMFD
AP		EQ 10GM BASE/VIAL	N61773 004		Mar	CMFD

CEFEPIME HYDROCHLORIDE

INJECTABLE; INJECTION

CEFEPIME HYDROCHLORIDE

AP	ACS DOBFAR	EQ 1GM BASE/VIAL	N65441 001	Mar 20, 2008	Mar	NEWA
AP		EQ 2GM BASE/VIAL	N65441 002	Mar 20, 2008	Mar	NEWA

CEFIXIME

TABLET; ORAL

SUPRAX

>D>	@ LUPIN	400MG	N65130 001	Feb 12, 2004	Apr	CMFD
>A>	+	400MG	N65130 001	Feb 12, 2004	Apr	CMFD

CEFPROZIL

TABLET; ORAL

CEFPROZIL

AB	APOTEX INC	250MG	N65327 001	Mar 26, 2008	Mar	NEWA
AB		500MG	N65327 002	Mar 26, 2008	Mar	NEWA

CEFTRIAZONE SODIUM

INJECTABLE; IM-IV

CEFTRIAZONE

AP	LUITPOLD	EQ 250MG BASE/VIAL	N65305 001	Jan 11, 2008	Jan	NEWA
AP		EQ 500MG BASE/VIAL	N65305 002	Jan 11, 2008	Jan	NEWA
AP		EQ 1GM BASE/VIAL	N65305 003	Jan 11, 2008	Jan	NEWA
AP		EQ 2GM BASE/VIAL	N65305 004	Jan 11, 2008	Jan	NEWA

CEFUROXIME AXETIL

FOR SUSPENSION; ORAL

CEFTIN

AB	GLAXOSMITHKLINE	EQ 125MG BASE/5ML	N50672 001	Jun 30, 1994	Jan	CFTG
AB	+	EQ 250MG BASE/5ML	N50672 002	Apr 29, 1997	Jan	CFTG

CEFUROXIME AXETIL

AB	RANBAXY	EQ 125MG BASE/5ML	N65323 001	Feb 05, 2008	Jan	NEWA
AB		EQ 250MG BASE/5ML	N65323 002	Feb 05, 2008	Jan	NEWA

TABLET; ORAL

CEFUROXIME AXETIL

AB	ORCHID HLTHCARE	EQ 125MG BASE	N65359 001	Feb 15, 2008	Jan	NEWA
AB		EQ 250MG BASE	N65359 002	Feb 15, 2008	Jan	NEWA
AB		EQ 500MG BASE	N65359 003	Feb 15, 2008	Jan	NEWA

CETIRIZINE HYDROCHLORIDE

SYRUP; ORAL

Zyrtec

+	MCNEIL CONSUMER	5MG/5ML	N20346 001	Sep 27, 1996	Jan	CAHN
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CHLORPHENIRAMINE MALEATE

TABLET; ORAL

CHLORPHENIRAMINE MALEATE

>D>	@ LEINER	4MG	N80786 001	Apr	CAHN
>A>	@ PVT FORM	4MG	N80786 001	Apr	CAHN

CHLORPROMAZINE HYDROCHLORIDE

TABLET; ORAL

CHLORPROMAZINE HYDROCHLORIDE

>D>	@ LEINER	25MG	N80340 001	Apr	CAHN
>D>	@	50MG	N80340 002	Apr	CAHN
>D>	@	200MG	N80340 003	Apr	CAHN
>A>	@ PVT FORM	25MG	N80340 001	Apr	CAHN
>A>	@	50MG	N80340 002	Apr	CAHN
>A>	@	200MG	N80340 003	Apr	CAHN

CICLESONIDE

AEROSOL, METERED; INHALATION

ALVESCO

	NYCOMED US	0.08MG/INH	N21658 002	Jan 10, 2008	Jan	NEWA
+		0.16MG/INH	N21658 003	Jan 10, 2008	Jan	NEWA

CIPROFLOXACIN

INJECTABLE; INJECTION

CIPRO IN DEXTROSE 5% IN PLASTIC CONTAINER

AP	+	BAYER PHARMS	200MG/100ML	N19857 001	Dec 26, 1990	Mar	CFTG
AP	+		400MG/200ML	N19857 002	Dec 26, 1990	Mar	CFTG
		CIPROFLOXACIN					
>A>	AP	CLARIS LIFESCIENCES	200MG/20ML (10MG/ML)	N78062 001	Apr 29, 2008	Apr	NEWA
>A>	AP		400MG/40ML (10MG/ML)	N78062 002	Apr 29, 2008	Apr	NEWA
		CIPROFLOXACIN IN DEXTROSE 5% IN PLASTIC CONTAINER					
AP		ACS DOBFAR INFO SA	200MG/100ML	N78252 001	Mar 18, 2008	Mar	NEWA
AP			400MG/200ML	N78252 002	Mar 18, 2008	Mar	NEWA
AP		BAXTER HLTHCARE	200MG/100ML	N77888 001	Mar 18, 2008	Mar	NEWA
AP			400MG/200ML	N77888 002	Mar 18, 2008	Mar	NEWA
AP		BEDFORD	200MG/100ML	N78114 001	Mar 18, 2008	Mar	NEWA
AP			400MG/200ML	N78114 002	Mar 18, 2008	Mar	NEWA
AP		CLARIS LIFESCIENCES	200MG/100ML	N78024 001	Mar 18, 2008	Mar	NEWA
AP			400MG/200ML	N78024 002	Mar 18, 2008	Mar	NEWA
>A>	AP	HIKMA FARMACEUTICA	200MG/100ML	N76757 001	Apr 21, 2008	Apr	NEWA
AP		HOSPIRA	200MG/100ML	N77753 001	Mar 18, 2008	Mar	NEWA
AP			400MG/200ML	N77753 002	Mar 18, 2008	Mar	NEWA
AP		TEVA PARENTERAL	200MG/100ML	N77138 001	Mar 18, 2008	Mar	NEWA
AP			400MG/200ML	N77138 002	Mar 18, 2008	Mar	NEWA

CIPROFLOXACIN HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

CIPROFLOXACIN HYDROCHLORIDE

AT		PHARMAFORCE	EQ 0.3% BASE	N78598 001	Jan 16, 2008	Jan	NEWA
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CITALOPRAM HYDROBROMIDE

TABLET; ORAL

CITALOPRAM HYDROBROMIDE

AB		MATRIX LABS INC	EQ 10MG BASE	N77042 001	Nov 05, 2004	Mar	CAHN
AB			EQ 20MG BASE	N77042 002	Nov 05, 2004	Mar	CAHN

## TABLET; ORAL

## CITALOPRAM HYDROBROMIDE

AB	MATRIX LABS INC	EQ 40MG BASE	N77042 003	Nov 05, 2004	Mar	CAHN
AB	NATCO PHARMA LTD	EQ 20MG BASE	N77141 002	Apr 10, 2008	Mar	NEWA
AB		EQ 40MG BASE	N77141 001	Apr 10, 2008	Mar	NEWA

>D> CITRIC ACID; MAGNESIUM OXIDE; SODIUM CARBONATE

## &gt;D&gt; SOLUTION; IRRIGATION

## &gt;D&gt; UROLOGIC G IN PLASTIC CONTAINER

>D>	+	HOSPIRA	3.24GM/100ML;380MG/100ML;430MG/100ML	N18904 001	May 27, 1983	Apr	DISC
>A>		@	3.24GM/100ML;380MG/100ML;430MG/100ML	N18904 001	May 27, 1983	Apr	DISC

CLINDAMYCIN PHOSPHATE

## SOLUTION; TOPICAL

## CLINDAMYCIN PHOSPHATE

>A>	@	BOCA PHARMA	EQ 1% BASE	N62930 001	Jun 28, 1989	Apr	CAHN
>D>	@	TEVA	EQ 1% BASE	N62930 001	Jun 28, 1989	Apr	CAHN

CLOBETASOL PROPIONATE

## AEROSOL, FOAM; TOPICAL

## CLOBETASOL PROPIONATE

AB		PERRIGO ISRAEL	0.05%	N77763 001	Mar 10, 2008	Feb	NEWA
AB	+	CONNETICS	0.05%	N21142 001	May 26, 2000	Feb	CFTG

CLOPIDOGREL BISULFATE

## TABLET; ORAL

## CLOPIDOGREL BISULFATE

AB		DR REDDYS LABS INC	EQ 75MG BASE	N76273 001	Jan 14, 2008	Jan	NEWA
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CLOZAPINE

## TABLET; ORAL

## CLOZAPINE

	@	TEVA	25MG	N75162 001	Apr 26, 2005	Mar	DISC
	@		100MG	N75162 002	Apr 26, 2005	Mar	DISC

CODEINE PHOSPHATE; PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

## SYRUP; ORAL

## TRIAFIN-C

+	ACTAVIS MID ATLANTIC	10MG/5ML;30MG/5ML;1.25MG/5ML	N88704 001	Mar 22, 1985	Feb	CRLD	
		TRIPROLIDINE HCL, PSEUDOEPHEDRINE HCL AND CODEINE PHOSPHATE					
	@	MORTON GROVE	10MG/5ML;30MG/5ML;1.25MG/5ML	N88833 001	Nov 16, 1984	Feb	DISC

COLCHICINE; PROBENECID

## TABLET; ORAL

## COL-PROBENECID

>D>	BP	+	WATSON LABS	0.5MG;500MG	N84279 001		Apr	CTEC
>A>	BP	+		0.5MG;500MG	N84279 001		Apr	CTEC
				PROBENECID AND COLCHICINE				
>A>	AB		CONCORD LABS NJ	0.5MG;500MG	N40618 001	May 13, 2008	Apr	NEWA

COLISTIMETHATE

INJECTABLE; INJECTION

COLISTIMETHATE

AP	APP PHARMS	EQ 150MG BASE/VIAL	N65364 001	Apr 17, 2008	Mar	NEWA
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COSYNTROPIN

SOLUTION; INTRAVENOUS

COSYNTROPIN

SANDOZ

0.25MG/ML (0.25MG/ML)

N22028 001	Feb 21, 2008	Feb	NEWA
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CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL

CYCLOBENZAPRINE HYDROCHLORIDE

AB	AMNEAL PHARM	10MG	N78218 001	Apr 18, 2008	Mar	NEWA	
>A>	AB	RANBAXY	5MG	N78722 001	May 12, 2008	Apr	NEWA
>A>	AB		7.5MG	N78722 002	May 12, 2008	Apr	NEWA
>A>	AB		10MG	N78722 003	May 12, 2008	Apr	NEWA
	@ SANDOZ	10MG	N73683 001	Feb 26, 1993	Feb	DISC	
>D>	WATSON LABS	7.5MG	N71611 003	Feb 03, 2006	Apr	CTEC	
>A>	AB	7.5MG	N71611 003	Feb 03, 2006	Apr	CTEC	
	@	10MG	N73143 001	Nov 27, 1991	Feb	DISC	
	@	10MG	N74436 001	Nov 30, 1994	Feb	DISC	

CYCLOPHOSPHAMIDE

INJECTABLE; INJECTION

CYCLOPHOSPHAMIDE

@ BAXTER HLTHCARE

100MG/VIAL

N88371 001	Jul 03, 1986	Jan	DISC
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@

200MG/VIAL

N88372 001	Jul 03, 1986	Jan	DISC
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@

500MG/VIAL

N88373 001	Jul 03, 1986	Jan	DISC
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@

1GM/VIAL

N88374 001	Sep 24, 1986	Jan	DISC
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LYOPHILIZED CYTOXAN

+	BRISTOL MYERS SQUIBB	100MG/VIAL	N12142 006	Dec 05, 1985	Jan	CTEC
+		200MG/VIAL	N12142 007	Dec 10, 1985	Jan	CTEC
+		500MG/VIAL	N12142 008	Jan 04, 1984	Jan	CTEC
+		1GM/VIAL	N12142 010	Sep 24, 1985	Jan	CTEC
+		2GM/VIAL	N12142 009	Dec 10, 1984	Jan	CTEC

NEOSAR

@ TEVA PARENTERAL

100MG/VIAL

N87442 001	Feb 16, 1982	Jan	DISC
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@

200MG/VIAL

N87442 002	Feb 16, 1982	Jan	DISC
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@

500MG/VIAL

N87442 003	Feb 16, 1982	Jan	DISC
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@

1GM/VIAL

N87442 004	Jul 08, 1983	Jan	DISC
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@

2GM/VIAL

N87442 005	Mar 30, 1989	Jan	DISC
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TABLET; ORAL

CYCLOPHOSPHAMIDE

ROXANE

25MG

N40032 001	Aug 17, 1999	Jan	CTEC
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+

50MG

N40032 002	Aug 17, 1999	Jan	CRLD
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CYTOXAN

@ BRISTOL MYERS SQUIBB

25MG

N12141 002		Jan	DISC
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@

50MG

N12141 001		Jan	DISC
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DARUNAVIR ETHANOLATE

TABLET; ORAL

PREZISTA

TIBOTEC

EQ 300MG BASE

N21976 001	Jun 23, 2006	Feb	CRLD
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+

EQ 600MG BASE

N21976 002	Feb 25, 2008	Feb	NEWA
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DEMECLOCYCLINE HYDROCHLORIDE

TABLET; ORAL

DEMECLOCYCLINE HYDROCHLORIDE

AB	AMNEAL PHARM	150MG	N65425 001	Feb 27, 2008	Feb	NEWA
AB		300MG	N65425 002	Feb 27, 2008	Feb	NEWA

DESVENLAFAXINE SUCCINATE

TABLET, EXTENDED RELEASE; ORAL

PRISTIQ

WYETH PHARMS INC EQ 50MG BASE

N21992 001 Feb 29, 2008 Feb NEWA

+ EQ 100MG BASE

N21992 002 Feb 29, 2008 Feb NEWA

DEXAMETHASONE

ELIXIR; ORAL

DEXAMETHASONE

AA	+ MORTON GROVE	0.5MG/5ML	N88254 001	Jul 27, 1983	Feb	CTNA
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TABLET; ORAL

DEXAMETHASONE

>D>	@ LEINER	0.75MG	N83420 001		Apr	CAHN
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>A>	@ PVT FORM	0.75MG	N83420 001		Apr	CAHN
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DEXCHLORPHENIRAMINE MALEATE

SYRUP; ORAL

DEXCHLORPHENIRAMINE MALEATE

	+ MORTON GROVE	2MG/5ML	N88251 001	Mar 23, 1984	Feb	CTNA
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TABLET; ORAL

DEXCHLORPHENIRAMINE MALEATE

	@ PLIVA	2MG	N88682 001	Jan 17, 1986	Feb	DISC
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DEXTROAMPHETAMINE SULFATE

SOLUTION; ORAL

DEXTROAMPHETAMINE SULFATE

	+ OUTLOOK PHARMS	5MG/5ML	N40776 001	Jan 29, 2008	Jan	NEWA
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DIAZEPAM

INJECTABLE; INJECTION

DIAZEPAM

	@ MARSAM PHARMS LLC	5MG/ML	N72397 001	Jan 29, 1993	Feb	DISC
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DICLOFENAC SODIUM

GEL; TOPICAL

SOLARAZE

	+ NYCOMED US	3%	N21005 001	Oct 16, 2000	Feb	CAHN
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SOLUTION/DROPS; OPHTHALMIC

DICLOFENAC SODIUM

AT	AKORN	0.1%	N77845 001	Apr 17, 2008	Mar	NEWA
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AT	ALCON	0.1%	N78031 001	Feb 06, 2008	Jan	NEWA
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DICLOXACILLIN SODIUM

FOR SUSPENSION; ORAL

DICLOXACILLIN SODIUM

	@ APOTHECON	EQ 62.5MG BASE/5ML	N61455 001		Jan	DISC
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DIGOXIN

## INJECTABLE; INJECTION

>D>		DIGOXIN PEDIATRIC					
>D>	AP	HOSPIRA	0.1MG/ML	N40092	001	Apr 25, 1996	Apr DISC
>A>		@	0.1MG/ML	N40092	001	Apr 25, 1996	Apr DISC
		LANOXIN PEDIATRIC					
>D>	AP	+ GLAXOSMITHKLINE	0.1MG/ML	N09330	004		Apr CTEC
>A>		+	0.1MG/ML	N09330	004		Apr CTEC

DILTIAZEM HYDROCHLORIDE

## INJECTABLE; INJECTION

## DILTIAZEM HYDROCHLORIDE

		@ HOSPIRA	5MG/ML	N75004	001	Feb 16, 2000	Feb DISC
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DIPHENHYDRAMINE HYDROCHLORIDE

## CAPSULE; ORAL

## DIPHENHYDRAMINE HYDROCHLORIDE

>D>		@ LEINER	25MG	N83027	001		Apr CAHN
>D>		@	50MG	N83027	002		Apr CAHN
		@ MUTUAL PHARM	25MG	N84506	001		Feb DISC
		@	25MG	N89488	001	Jan 02, 1987	Feb DISC
>A>		@ PVT FORM	25MG	N83027	001		Apr CAHN
>A>		@	50MG	N83027	002		Apr CAHN

## ELIXIR; ORAL

## DIPHENHYDRAMINE HYDROCHLORIDE

>D>		@ LEINER	12.5MG/5ML	N85287	001		Apr CAHN
>A>		@ PVT FORM	12.5MG/5ML	N85287	001		Apr CAHN

DIPYRIDAMOLE

## TABLET; ORAL

## DIPYRIDAMOLE

>A>	AB	LANNETT	25MG	N40898	001	Apr 23, 2008	Apr NEWA
>A>	AB		50MG	N40898	002	Apr 23, 2008	Apr NEWA
>A>	AB		75MG	N40898	003	Apr 23, 2008	Apr NEWA
	AB	ZYDUS PHARMS USA INC	25MG	N40874	001	Jan 28, 2008	Jan NEWA
	AB		50MG	N40874	002	Jan 28, 2008	Jan NEWA
	AB		75MG	N40874	003	Jan 28, 2008	Jan NEWA

DOBUTAMINE HYDROCHLORIDE

## INJECTABLE; INJECTION

## DOBUTAMINE HYDROCHLORIDE

		@ MARSAM PHARMS LLC	EQ 12.5MG BASE/ML	N74995	001	Mar 31, 1998	Feb DISC
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DONEPEZIL HYDROCHLORIDE

## TABLET; ORAL

## ARICEPT

>D>		EISAI MEDCL RES	5MG	N20690	002	Nov 25, 1996	Apr CFTG
>A>	AB		5MG	N20690	002	Nov 25, 1996	Apr CFTG
>D>		+	10MG	N20690	001	Nov 25, 1996	Apr CFTG
>A>	AB	+	10MG	N20690	001	Nov 25, 1996	Apr CFTG
		DONEPEZIL HYDROCHLORIDE					
>A>	AB	TEVA	5MG	N77344	001	Apr 28, 2008	Apr NEWA
>A>	AB		10MG	N77344	002	Apr 28, 2008	Apr NEWA

DOXEPIN HYDROCHLORIDE

CREAM; TOPICAL

ZONALON

	+	NYCOMED US	5%	N20126 001	Apr 01, 1994	Feb	CAHN
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DOXYCYCLINE

CAPSULE, DELAYED RELEASE; ORAL

ORACEA

>D>	+	COLLAGENEX PHARMS	40MG	N50805 001	May 26, 2006	Apr	CAHN
>A>	+	GALDERMA LABS LP	40MG	N50805 001	May 26, 2006	Apr	CAHN

DOXYCYCLINE HYCLATE

CAPSULE; ORAL

DOXYCYCLINE HYCLATE

>D>	@	LEINER	EQ 100MG BASE	N62631 002	Jul 24, 1986	Apr	CAHN
>A>	@	PVT FORM	EQ 100MG BASE	N62631 002	Jul 24, 1986	Apr	CAHN

TABLET; ORAL

PERIOSTAT

>D>	AB	+	COLLAGENEX PHARMS	EQ 20MG BASE	N50783 001	Feb 02, 2001	Apr	CAHN
>A>	AB	+	GALDERMA LABS LP	EQ 20MG BASE	N50783 001	Feb 02, 2001	Apr	CAHN

DROSPIRENONE; ETHINYL ESTRADIOL

TABLET; ORAL-28

>A>			DROSPIRENONE AND ETHINYL ESTRADIOL					
>A>	AB		BARR	3MG;0.03MG	N77527 001	May 09, 2008	Apr	NEWA
			YASMIN					
>D>		+	BAYER HLTHCARE	3MG;0.03MG	N21098 001	May 11, 2001	Apr	CFTG
>A>	AB	+		3MG;0.03MG	N21098 001	May 11, 2001	Apr	CFTG

ECONAZOLE NITRATE

CREAM; TOPICAL

SPECTAZOLE

	@	ORTHONEUTROGENA	1%	N18751 001	Dec 23, 1982	Feb	CAHN
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EDETATE DISODIUM

INJECTABLE; INJECTION

EDETATE DISODIUM

	@	APOTEX INC	150MG/ML	N40376 001	Nov 04, 2002	Jan	DISC
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EDROPHONIUM CHLORIDE

INJECTABLE; INJECTION

ENLON

	@	BAXTER HLTHCARE CORP	10MG/ML	N88873 001	Aug 06, 1985	Feb	DISC
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EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HYDROCHLORIDE AND EPINEPHRINE

>D>	AP		HOSPIRA	0.005MG/ML;1.5%	N89650 001	Jun 21, 1988	Apr	DISC
>A>		@		0.005MG/ML;1.5%	N89650 001	Jun 21, 1988	Apr	DISC
>A>	AP			0.01MG/ML;2%	N78772 001	May 12, 2008	Apr	NEWA
>A>	AP			0.02MG/ML;2%	N78772 002	May 12, 2008	Apr	NEWA
			XYLOCAINE W/ EPINEPHRINE					
>D>		+	DENTSPLY PHARM	0.01MG/ML;2%	N21381 001		Apr	CFTG
>A>	AP	+		0.01MG/ML;2%	N21381 001		Apr	CFTG
>D>		+		0.02MG/ML;2%	N21381 002		Apr	CFTG

INJECTABLE; INJECTION  
XYLOCAINE W/ EPINEPHRINE

>A> AP + DENTSPLY PHARM 0.02MG/ML;2% N21381 002 Apr CFTG

EPOPROSTENOL SODIUM

INJECTABLE; INJECTION

>A> EPOPROSTENOL SODIUM  
 >A> AP TEVA PARENTERAL EQ 0.5MG BASE/VIAL N78396 001 Apr 23, 2008 Apr NEWA  
 >A> AP EQ 1.5MG BASE/VIAL N78396 002 Apr 23, 2008 Apr NEWA  
 FLOLAN  
 >D> + GLAXOSMITHKLINE EQ 0.5MG BASE/VIAL N20444 001 Sep 20, 1995 Apr CFTG  
 >A> AP + EQ 0.5MG BASE/VIAL N20444 001 Sep 20, 1995 Apr CFTG  
 >D> + EQ 1.5MG BASE/VIAL N20444 002 Sep 20, 1995 Apr CFTG  
 >A> AP + EQ 1.5MG BASE/VIAL N20444 002 Sep 20, 1995 Apr CFTG

ERYTHROMYCIN

SWAB; TOPICAL  
ERYCETE

@ ORTHONEUTROGENA 2% N50594 001 Feb 15, 1985 Feb CAHN

ESOMEPRAZOLE MAGNESIUM

FOR SUSPENSION, DELAYED RELEASE; ORAL  
NEXIUM

ASTRAZENECA EQ 10MG BASE/PACKET N22101 001 Feb 27, 2008 Feb NEWA

ESTRADIOL

GEL, METERED; TRANSDERMAL  
ELESTRIN

+ BRADLEY PHARMS 0.06% (0.87GM/ACTIVATION) N21813 001 Dec 15, 2006 Jan CTEC  
 + NYCOMED US 0.06% (0.87GM/ACTIVATION) N21813 001 Dec 15, 2006 Feb CAHN  
 ESTROGEL  
 + ASCEND 0.06% (1.25GM/ACTIVATION) N21166 002 Feb 09, 2004 Jan CTEC

ESTRADIOL; NORETHINDRONE ACETATE

TABLET; ORAL  
ACTIVELLA

AB + NOVO NORDISK INC 1MG;0.5MG N20907 001 Nov 18, 1998 Mar CFTG  
 ESTRADIOL AND NORETHINDRONE ACETATE  
 AB BRECKENRIDGE PHARM 1MG;0.5MG N78324 001 Apr 17, 2008 Mar NEWA

ESTROGENS, ESTERIFIED

TABLET; ORAL

ESTERIFIED ESTROGENS

>D> @ LEINER 0.625MG N83414 001 Apr CAHN  
 >D> @ 1.25MG N83765 001 Apr CAHN  
 >D> @ 2.5MG N85907 001 Apr CAHN  
 >A> @ PVT FORM 0.625MG N83414 001 Apr CAHN  
 >A> @ 1.25MG N83765 001 Apr CAHN  
 >A> @ 2.5MG N85907 001 Apr CAHN  
 FEMOGEN  
 >D> @ LEINER 0.625MG N85076 001 Apr CAHN  
 >D> @ 1.25MG N85008 001 Apr CAHN  
 >D> @ 2.5MG N85007 001 Apr CAHN  
 >A> @ PVT FORM 0.625MG N85076 001 Apr CAHN  
 >A> @ 1.25MG N85008 001 Apr CAHN  
 >A> @ 2.5MG N85007 001 Apr CAHN



ETHAMBUTOL HYDROCHLORIDE

	TABLET; ORAL				
	MYAMBUTOL				
AB	STAT-TRADE	100MG	N16320 001	Jan	CAHN
	@	200MG	N16320 002	Jan	CAHN
AB		400MG	N16320 003	Jan	CAHN
	@	500MG	N16320 004	Jan	CAHN

ETHIONAMIDE

	TABLET; ORAL				
	TRECATOR				
>A>					
>A>	+	WYETH PHARMS INC	250MG	N13026 002	Apr CTNA
>D>		TRECATOR-SC			
>D>	+	WYETH PHARMS INC	250MG	N13026 002	Apr CTNA

ETRAVIRINE

	TABLET; ORAL				
	INTELENCE				
	+	TIBOTEC	100MG	N22187 001	Jan 18, 2008 Jan NEWA

FAMOTIDINE

	INJECTABLE; INJECTION				
	FAMOTIDINE				
	@	APOTEX INC	10MG/ML	N75942 001	Aug 02, 2002 Feb DISC
	@	HOSPIRA	10MG/ML	N75905 001	Nov 23, 2001 Feb DISC
	TABLET; ORAL				
	FAMOTIDINE				
	@	SANDOZ	20MG	N75793 001	Apr 16, 2001 Feb DISC
	@		40MG	N75793 002	Apr 16, 2001 Feb DISC

FELODIPINE

	TABLET, EXTENDED RELEASE; ORAL				
	FELODIPINE				
AB	MYLAN	2.5MG	N78855 001	Apr 17, 2008 Mar	NEWA
AB		5MG	N78855 002	Apr 17, 2008 Mar	NEWA
AB		10MG	N78855 003	Apr 17, 2008 Mar	NEWA

FENOFIBRATE

	TABLET; ORAL				
	FENOFIBRATE				
AB	IMPAX LABS	54MG	N76509 001	Mar 26, 2008 Mar	NEWA
AB		160MG	N76509 002	Mar 26, 2008 Mar	NEWA
>D>		LIFECYCLE PHARMA AS	40MG	N22118 001	Aug 10, 2007 Apr CAHN
>D>	+		120MG	N22118 002	Aug 10, 2007 Apr CAHN
>A>		SCIELE PHARMA INC	40MG	N22118 001	Aug 10, 2007 Apr CAHN
>A>	+		120MG	N22118 002	Aug 10, 2007 Apr CAHN

FENOPROFEN CALCIUM

	TABLET; ORAL				
	FENOPROFEN CALCIUM				
	@	WATSON LABS	EQ 600MG BASE	N72407 001	Aug 17, 1988 Feb DISC
	@		EQ 600MG BASE	N72602 001	Oct 11, 1988 Feb DISC

FEXOFENADINE HYDROCHLORIDE

TABLET; ORAL

FEXOFENADINE HYDROCHLORIDE

AB	MYLAN	30MG	N77081 002	Apr 11, 2008	Mar	NEWA
AB		60MG	N77081 003	Apr 11, 2008	Mar	NEWA

FLECAINIDE ACETATE

TABLET; ORAL

FLECAINIDE ACETATE

AB	AMNEAL PHARM	50MG	N75442 001	Jul 31, 2001	Feb	CAHN
AB		100MG	N75442 002	Jul 31, 2001	Feb	CAHN
AB		150MG	N75442 003	Jul 31, 2001	Feb	CAHN

FLUMAZENIL

INJECTABLE; INJECTION

FLUMAZENIL

>A>	AP	AKORN STRIDES	0.5MG/5ML(0.1MG/ML)	N78595 001	May 13, 2008	Apr	NEWA
>A>	AP		1MG/10ML(0.1MG/ML)	N78595 002	May 13, 2008	Apr	NEWA

FLUOCINONIDE

CREAM; TOPICAL

FLUOCINONIDE

@ TARO

0.05%

N71500 001 Jun 10, 1987 Feb DISC

SOLUTION; TOPICAL

FLUOCINONIDE

@ TARO

0.05%

N72857 001 Aug 02, 1989 Feb DISC

FLUOROURACIL

CREAM; TOPICAL

EFUDEX

AB	+	VALEANT PHARM INTL	5%	N16831 003		Mar	CFTG
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FLUOROURACIL

AB		SPEAR PHARMS	5%	N77524 001	Apr 11, 2008	Mar	NEWA
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FLUOXETINE HYDROCHLORIDE

CAPSULE; ORAL

FLUOXETINE

AB	AUROBINDO PHARMA	EQ 10MG BASE	N78619 001	Jan 31, 2008	Jan	NEWA
AB		EQ 20MG BASE	N78619 002	Jan 31, 2008	Jan	NEWA
AB		EQ 40MG BASE	N78619 003	Jan 31, 2008	Jan	NEWA
AB	WOCKHARDT	EQ 10MG BASE	N78143 001	Jan 16, 2008	Jan	NEWA
AB		EQ 20MG BASE	N78143 002	Jan 16, 2008	Jan	NEWA
AB		EQ 40MG BASE	N78143 003	Jan 16, 2008	Jan	NEWA

FLUTICASONE PROPIONATE

SPRAY, METERED; NASAL

FLUTICASONE PROPIONATE

AB	HI TECH PHARMA	0.05MG/SPRAY	N77570 001	Jan 16, 2008	Jan	NEWA
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FLUVOXAMINE MALEATE

CAPSULE, EXTENDED RELEASE; ORAL

LUVOX CR

SOLVAY

100MG

N22033 001 Feb 28, 2008 Feb NEWA

+

150MG

N22033 002 Feb 28, 2008 Feb NEWA

TABLET; ORALLUVOX

>A>	AB	JAZZ	25MG	N21519 001	Dec 20, 2007	Apr	CAHN
>A>	AB		50MG	N21519 002	Dec 20, 2007	Apr	CAHN
>A>	AB		100MG	N21519 003	Dec 20, 2007	Apr	CAHN
>D>	AB	SOLVAY	25MG	N21519 001	Dec 20, 2007	Apr	CAHN
>D>	AB		50MG	N21519 002	Dec 20, 2007	Apr	CAHN
>D>	AB		100MG	N21519 003	Dec 20, 2007	Apr	CAHN

FOMEPIZOLEINJECTABLE; INJECTIONFOMEPIZOLE

AP		NAVINTA LLC	1.5GM/1.5ML (1GM/ML)	N78537 001	Mar 06, 2008	Feb	NEWA
AP		SYNERX PHARMA	1.5GM/1.5ML (1GM/ML)	N78639 001	Mar 03, 2008	Feb	NEWA

FOSAPREPITANT DIMEGLUMINEPOWDER; INTRAVENOUSEMEND

+		MERCK AND CO INC	EQ 115MG BASE/VIAL	N22023 001	Jan 25, 2008	Jan	NEWA
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FOSPHENYTOIN SODIUMINJECTABLE; INJECTIONFOSPHENYTOIN SODIUM

AP		AKORN STRIDES	EQ 50MG PNEYTOIN NA/ML	N78476 001	Mar 18, 2008	Mar	NEWA
AP		SUN PHARM INDS	EQ 50MG PHENYTOIN NA/ML	N78417 001	Mar 18, 2008	Mar	NEWA

FUROSEMIDEINJECTABLE; INJECTIONFUROSEMIDE

>D>	AP	HOSPIRA	10MG/ML	N74337 001	Oct 31, 1994	Apr	DISC
>A>		@	10MG/ML	N74337 001	Oct 31, 1994	Apr	DISC

GABAPENTINCAPSULE; ORALGABAPENTIN

AB		AUROBINDO PHARM	100MG	N78787 001	Jan 31, 2008	Jan	NEWA
AB			300MG	N78787 002	Jan 31, 2008	Jan	NEWA
AB			400MG	N78787 003	Jan 31, 2008	Jan	NEWA
		@ MUTUAL PHARM	100MG	N76537 001	Jun 30, 2005	Mar	DISC
		@	300MG	N76537 002	Jun 30, 2005	Mar	DISC
		@	400MG	N76537 003	Jun 30, 2005	Mar	DISC

GLIPIZIDE; METFORMIN HYDROCHLORIDETABLET; ORALGLIPIZIDE AND METFORMIN HYDROCHLORIDE

AB		CARACO	2.5MG;250MG	N77620 001	Jan 11, 2008	Jan	NEWA
AB			2.5MG;500MG	N77620 002	Jan 11, 2008	Jan	NEWA
AB			5MG;500MG	N77620 003	Jan 11, 2008	Jan	NEWA

GLUTAMINEFOR SOLUTION; ORALNUTRESTORE

+		NUTRITIONAL RESTART	5GM/PACKET	N21667 001	Jun 10, 2004	Mar	CMFD
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GLYCOPYRROLATE

TABLET; ORAL

GLYCOPYRROLATE

AA	INDICUS PHARMA	1MG	N40847 001	Mar 21, 2008	Mar	NEWA
AA		2MG	N40847 002	Mar 21, 2008	Mar	NEWA

GRANISETRON HYDROCHLORIDE

INJECTABLE; INJECTION

GRANISETRON HYDROCHLORIDE

>A>	AP	EBEWE PARENTA	EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML)	N78808 001	Apr 29, 2008	Apr	NEWA
	AP	WOCKHARDT USA	EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML)	N78566 001	Feb 29, 2008	Feb	NEWA

SOLUTION; ORAL

GRANISETRON HYDROCHLORIDE

AA	CYPRESS PHARM	EQ 2MG BASE/10ML	N78334 001	Feb 28, 2008	Feb	NEWA
AA	+ ROCHE	EQ 2MG BASE/10ML	N21238 001	Jun 27, 2001	Feb	CFTG

KYTRIL

TABLET; ORAL

GRANISETRON HYDROCHLORIDE

AB	APOTEX INC	EQ 1MG BASE	N78843 001	Feb 27, 2008	Feb	NEWA
AB	CIPLA LTD	EQ 1MG BASE	N78037 001	Feb 27, 2008	Feb	NEWA
AB	MYLAN	EQ 1MG BASE	N78725 001	Jan 30, 2008	Jan	NEWA
AB	ORCHID HLTHCARE	EQ 1MG BASE	N78678 001	Feb 13, 2008	Jan	NEWA

GRISEOFULVIN, MICROCRYSTALLINE

SUSPENSION; ORAL

GRIFULVIN V

AB	+ ORTHONEUTROGENA	125MG/5ML	N62483 001	Jan 26, 1984	Feb	CAHN
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GRISEOFULVIN

>A>	AB	PERRIGO CO TENNESSEE	125MG/5ML	N65200 001	Mar 02, 2005	Apr	CAHN
>D>	AB	STIEFEL	125MG/5ML	N65200 001	Mar 02, 2005	Apr	CAHN

TABLET; ORAL

FULVICIN-U/F

@ SCHERING

@

		250MG	N60569 002		Mar	DISC
		500MG	N60569 001		Mar	DISC

GRIFULVIN V

		ORTHONEUTROGENA	125MG	N62279 001		Feb	CAHN
			250MG	N62279 002		Mar	CRLD
AB			250MG	N62279 002		Feb	CAHN
			500MG	N62279 003		Mar	CRLD
AB			500MG	N62279 003		Feb	CAHN

GUANFACINE HYDROCHLORIDE

TABLET; ORAL

GUANFACINE HYDROCHLORIDE

AB	AMNEAL PHARM	EQ 1MG BASE	N75109 001	Nov 25, 1998	Feb	CAHN
AB		EQ 2MG BASE	N75109 002	Nov 25, 1998	Feb	CAHN

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN SODIUM PRESERVATIVE FREE

	+ HOSPIRA	2,500 UNITS/ML	N05264 014	Apr 07, 1986	Jan	CTEC
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HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE

SYRUP; ORAL

HYDROCODONE BITARTRATE AND HOMATROPINE METHYLBROMIDE

AA	HI TECH PHARMA	1.5MG/5ML;5MG/5ML	N40613	001	Feb 08, 2008	Jan	NEWA
AA	MORTON GROVE	1.5MG/5ML;5MG/5ML	N88008	001	Mar 03, 1983	Feb	CTNA

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

HYDRALAZINE HYDROCHLORIDE

	@ MUTUAL PHARM	10MG	N89359	001	Jul 25, 1986	Feb	DISC
	@	25MG	N89258	001	May 05, 1986	Feb	DISC
	@	50MG	N89259	001	May 05, 1986	Feb	DISC

HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

HYDROCHLOROTHIAZIDE

AB	CADISTA PHARMS	12.5MG	N78391	001	Feb 11, 2008	Jan	NEWA
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TABLET; ORAL

HYDROCHLOROTHIAZIDE

>D>	@ LEINER	50MG	N86597	001		Apr	CAHN
>A>	@ PVT FORM	50MG	N86597	001		Apr	CAHN

HYDROXYCHLOROQUINE SULFATE

TABLET; ORAL

HYDROXYCHLOROQUINE SULFATE

AB	IPCA LABS LTD	200MG	N40766	001	Jun 14, 2007	Jan	CMFD
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HYDROXYUREA

TABLET; ORAL

HYDROXYUREA

	@ BARR	1GM	N75734	001	Aug 29, 2000	Jan	DISC
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HYDROXYZINE

TABLET; ORAL

HYDROXYZINE HYDROCHLORIDE

AB	INVAGEN PHARMS	10MG	N40812	001	Mar 12, 2008	Feb	NEWA
AB		25MG	N40812	002	Mar 12, 2008	Feb	NEWA
AB		50MG	N40812	003	Mar 12, 2008	Feb	NEWA

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL

HYDROXYZINE HYDROCHLORIDE

AB	INVAGEN PHARMS	10MG	N40812	001	Mar 12, 2008	Mar	CAIN
AB		25MG	N40812	002	Mar 12, 2008	Mar	CAIN
AB		50MG	N40812	003	Mar 12, 2008	Mar	CAIN
AB	NORTHSTAR HLTHCARE	10MG	N40841	001	Mar 31, 2008	Mar	NEWA
AB		25MG	N40842	001	Mar 31, 2008	Mar	NEWA
AB		50MG	N40840	001	Mar 31, 2008	Mar	NEWA

IBUPROFEN

TABLET; ORAL

IBUPROFEN

>D>	AB	LEINER	300MG	N71266	001	Oct 15, 1986	Apr	DISC
>A>		@	300MG	N71266	001	Oct 15, 1986	Apr	DISC

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL

IMIPRAMINE HYDROCHLORIDE

AB	ACTAVIS TOTOWA	10MG	N40753 001	Feb 28, 2008	Feb	NEWA
AB		25MG	N40752 001	Feb 28, 2008	Feb	NEWA
AB		50MG	N40751 001	Feb 28, 2008	Feb	NEWA

IMIPRAMINE PAMOATE

CAPSULE; ORAL

TOFRANIL-PM

+	TYCO HLTHCARE	EQ 75MG HCL	N17090 001		Jan	CRLD
		EQ 150MG HCL	N17090 002		Jan	CRLD

INDAPAMIDE

TABLET; ORAL

INDAPAMIDE

AB	+ MYLAN	2.5MG	N74461 001	Mar 27, 1996	Mar	CRLD
	LOZOL					
	@ SANOFI AVENTIS US	1.25MG	N18538 002	Apr 29, 1993	Mar	DISC
	@	2.5MG	N18538 001	Jul 06, 1983	Mar	DISC

INDOMETHACIN

CAPSULE; ORAL

INDOCIN

@	IROKO PHARMS	25MG	N16059 001		Feb	CAHN
@		50MG	N16059 002		Feb	CAHN

INDOMETHACIN

AB	IVAX PHARMS	25MG	N70719 001	Feb 12, 1986	Jan	CMFD
AB		50MG	N70756 001	Feb 12, 1986	Jan	CMFD

CAPSULE, EXTENDED RELEASE; ORAL

INDOCIN SR

@	IROKO PHARMS	75MG	N18185 001	Feb 23, 1982	Feb	CAHN
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SUPPOSITORY; RECTAL

INDOCIN

@	IROKO PHARMS	50MG	N17814 001	Aug 13, 1984	Feb	CAHN
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IRINOTECAN HYDROCHLORIDE

INJECTABLE; INJECTION

CAMPTOSAR

AP	+ PFIZER INC	40MG/2ML (20MG/ML)	N20571 001	Jun 14, 1996	Feb	CFTG
AP	+	100MG/5ML (20MG/ML)	N20571 002	Jun 14, 1996	Feb	CFTG

IRINOTECAN HYDROCHLORIDE

AP	ACTAVIS TOTOWA	40MG/2ML (20MG/ML)	N78589 001	Feb 27, 2008	Feb	NEWA
AP		100MG/5ML (20MG/ML)	N78589 002	Feb 27, 2008	Feb	NEWA
AP	APP PHARMS	40MG/2ML (20MG/ML)	N77776 001	Feb 27, 2008	Feb	NEWA
AP		100MG/5ML (20MG/ML)	N77776 002	Feb 27, 2008	Feb	NEWA
AP	DABUR ONCOLOGY PLC	40MG/2ML (20MG/ML)	N78188 001	Feb 27, 2008	Feb	NEWA
AP		100MG/5ML (20MG/ML)	N78188 002	Feb 27, 2008	Feb	NEWA
AP	HOSPIRA	40MG/2ML (20MG/ML)	N77915 001	Feb 27, 2008	Feb	NEWA
AP		100MG/5ML (20MG/ML)	N77915 002	Feb 27, 2008	Feb	NEWA
	+	500MG/25ML (20MG/ML)	N78796 001	Feb 27, 2008	Feb	NEWA
AP	SANDOZ	40MG/2ML (20MG/ML)	N77994 001	Feb 27, 2008	Feb	NEWA
AP		100MG/5ML (20MG/ML)	N77994 002	Feb 27, 2008	Feb	NEWA
>A>	AP	SUN PHARMA GLOBAL	N78805 001	Apr 21, 2008	Apr	NEWA
>A>	AP		N78805 002	Apr 21, 2008	Apr	NEWA

## INJECTABLE; INJECTION

## IRINOTECAN HYDROCHLORIDE

AP	TEVA PARENTERAL	40MG/2ML (20MG/ML)	N77260 001	Feb 27, 2008	Feb	NEWA
AP		100MG/5ML (20MG/ML)	N77260 002	Feb 27, 2008	Feb	NEWA
AP	WATSON LABS	40MG/2ML (20MG/ML)	N77219 001	Feb 20, 2008	Feb	NEWA
AP		100MG/5ML (20MG/ML)	N77219 002	Feb 20, 2008	Feb	NEWA

ISONIAZID

## TABLET; ORAL

## ISONIAZID

@	MUTUAL PHARM	300MG	N83633 001		Mar	DISC
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ISOPROTERENOL HYDROCHLORIDE

## INJECTABLE; INJECTION

## ISOPROTERENOL HYDROCHLORIDE

>D>	HOSPIRA	0.02MG/ML	N83283 001		Apr	DISC
>A>	@	0.02MG/ML	N83283 001		Apr	DISC

ISOSORBIDE DINITRATE

## TABLET; SUBLINGUAL

## ISOSORBIDE DINITRATE

AB	+ WATSON LABS	5MG	N86031 001	Sep 29, 1987	Jan	CRLD
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## TABLET, EXTENDED RELEASE; ORAL

## ISOSORBIDE DINITRATE

AB	COREPHARMA	40MG	N40723 001	Mar 17, 2008	Mar	NEWA
AB	+ INWOOD LABS	40MG	N40009 001	Dec 30, 1998	Mar	CTEC

KETOROLAC TROMETHAMINE

## INJECTABLE; INJECTION

## KETOROLAC TROMETHAMINE

AP	LUITPOLD	15MG/ML	N78145 001	Jan 14, 2008	Jan	NEWA
AP		30MG/ML	N78145 002	Jan 14, 2008	Jan	NEWA

LEUPROLIDE ACETATE

## IMPLANT; IMPLANTATION

## VIADUR

+ JOHNSON AND JOHNSON	EQ 65MG BASE	N21088 001	Mar 03, 2000	Feb	CAHN
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## INJECTABLE; INJECTION

## LUPRON

>A>	AP	+ ABBOTT ENDO	1MG/0.2ML	N19010 001	Apr 09, 1985	Apr	CAHN
>D>	AP	+ TAP PHARM	1MG/0.2ML	N19010 001	Apr 09, 1985	Apr	CAHN

## LUPRON DEPOT

>A>	+ ABBOTT ENDO	3.75MG/VIAL	N20011 001	Oct 22, 1990	Apr	CAHN
>A>	+ TAP PHARM	7.5MG/VIAL	N19732 001	Jan 26, 1989	Apr	CAHN
>A>	+ TAP PHARM	22.5MG/VIAL	N20517 001	Dec 22, 1995	Apr	CAHN
>D>	+ ABBOTT ENDO	3.75MG/VIAL	N20011 001	Oct 22, 1990	Apr	CAHN
>D>	+ TAP PHARM	7.5MG/VIAL	N19732 001	Jan 26, 1989	Apr	CAHN
>D>	+ TAP PHARM	22.5MG/VIAL	N20517 001	Dec 22, 1995	Apr	CAHN

## LUPRON DEPOT-3

>A>	+ ABBOTT ENDO	11.25MG/VIAL	N20708 001	Mar 07, 1997	Apr	CAHN
>D>	+ TAP PHARM	11.25MG/VIAL	N20708 001	Mar 07, 1997	Apr	CAHN

## LUPRON DEPOT-4

>A>	+ ABBOTT ENDO	30MG/VIAL	N20517 002	May 30, 1997	Apr	CAHN
>D>	+ TAP PHARM	30MG/VIAL	N20517 002	May 30, 1997	Apr	CAHN

## LUPRON DEPOT-PED

>A>	@ ABBOTT ENDO	3.75MG/VIAL, 7.5MG/VIAL	N20263 003	Apr 16, 1993	Apr	CAHN
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INJECTABLE; INJECTIONLUPRON DEPOT-PED

>A>	+	ABBOTT ENDO	7.5MG/VIAL	N20263 002	Apr 16, 1993	Apr	CAHN
>A>	@		3.75MG/VIAL,7.5MG/VIAL	N20263 003	Apr 16, 1993	Apr	CAHN
>A>	@		7.5MG/VIAL,7.5MG/VIAL	N20263 004	Apr 16, 1993	Apr	CAHN
>A>	+		11.25MG/VIAL	N20263 005	Jan 21, 1994	Apr	CAHN
>A>	+		15MG/VIAL	N20263 006	Jan 21, 1994	Apr	CAHN
>D>	@	TAP PHARM	3.75MG/VIAL,7.5MG/VIAL	N20263 003	Apr 16, 1993	Apr	CAHN
>D>	@		7.5MG/VIAL,7.5MG/VIAL	N20263 004	Apr 16, 1993	Apr	CAHN
>D>	@		3.75MG/VIAL,7.5MG/VIAL	N20263 003	Apr 16, 1993	Apr	CAHN
>D>	+		7.5MG/VIAL	N20263 002	Apr 16, 1993	Apr	CAHN
>D>	+		11.25MG/VIAL	N20263 005	Jan 21, 1994	Apr	CAHN
>D>	+		15MG/VIAL	N20263 006	Jan 21, 1994	Apr	CAHN

LEVALBUTEROL HYDROCHLORIDESOLUTION; INHALATIONLEVALBUTEROL HYDROCHLORIDE

AN		BREATH LTD	EQ 0.0103% BASE	N77756 003	Apr 09, 2008	Mar	NEWA
AN			EQ 0.021% BASE	N77756 001	Apr 09, 2008	Mar	NEWA
AN			EQ 0.042% BASE	N77756 002	Apr 09, 2008	Mar	NEWA
		XOPENEX					
AN	+	SEPRACOR	EQ 0.0103% BASE	N20837 003	Jan 30, 2002	Mar	CFTG
AN	+		EQ 0.021% BASE	N20837 001	Mar 25, 1999	Mar	CFTG
AN	+		EQ 0.042% BASE	N20837 002	Mar 25, 1999	Mar	CFTG

LEVOCETIRIZINE DIHYDROCHLORIDESOLUTION; ORALXYZAL

	+	UCB INC	2.5MG/5ML	N22157 001	Jan 28, 2008	Jan	NEWA
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LEVOLEUCOVORIN CALCIUMPOWDER; IV (INFUSION)LEVOLEUCOVORIN

	+	SPECTRUM PHARMS	EQ 50MG BASE/VIAL	N20140 001	Mar 07, 2008	Mar	NEWA
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LEVONORDEFRIN; MEPIVACAINE HYDROCHLORIDEINJECTABLE; INJECTIONPOLOCAINE W/ LEVONORDEFRIN

AP	+	DENTSPLY PHARM	0.05MG/ML;2%	N89517 001	Apr 14, 1988	Jan	CRLD
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LEVOTHYROXINE SODIUM\*\*

\*\*Refer to Annual Edition Preface Section 1.8 Levothyroxine Sodium for amplifying information

TABLET; ORALLEVOXYL

AB1, AB3	+	KING PHARMS	0.2MG	N21301 011	May 25, 2001	Jan	CRLD
	@		0.3MG	N21301 012	May 25, 2001	Jan	DISC
		UNITHROID					
AB1, AB2, AB3		STEVENS J	0.137MG	N21210 012	Feb 08, 2008	Feb	NEWA

LIDOCAINE HYDROCHLORIDEINJECTABLE; INJECTIONXYLOCAINE PRESERVATIVE FREE

>D>	AP	ABRAXIS BIOSCIENCE	1%	N16801 005	Jan 19, 1988	Apr	CAHN
>D>	AP	+	2%	N16801 001		Apr	CAHN



INJECTABLE; INJECTIONXYLOCAINE PRESERVATIVE FREE

>D>	AP	ABRAXIS BIOSCIENCE	4%	N16801 002		Apr	CAHN
>D>	AP	+	10%	N16801 003		Apr	CAHN
>D>	AP	+	20%	N16801 004		Apr	CAHN
>A>	AP	APP PHARMS	1%	N16801 005	Jan 19, 1988	Apr	CAHN
>A>	AP	+	2%	N16801 001		Apr	CAHN
>A>	AP		4%	N16801 002		Apr	CAHN
>A>	AP	+	10%	N16801 003		Apr	CAHN
>A>	AP	+	20%	N16801 004		Apr	CAHN

LITHIUM CARBONATECAPSULE; ORALESKALITH

AB		NOVEN THERAP	300MG	N16860 001		Jan	CAHN
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LITHIUM CARBONATE

AB	+	ROXANE	600MG	N17812 003	Jan 28, 1987	Mar	CTEC
AB		WEST WARD	600MG	N78763 001	Apr 15, 2008	Mar	NEWA

TABLET, EXTENDED RELEASE; ORALLITHOBID

AB	+	NOVEN THERAP	300MG	N18027 001		Jan	CAHN
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LOVASTATINTABLET; ORALLOVASTATIN

AB		LUPIN	10MG	N78296 001	Mar 14, 2008	Mar	NEWA
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LUBIPROSTONECAPSULE; ORALAMITIZA

>A>		SUCAMPO PHARMS	8UGM	N21908 002	Apr 29, 2008	Apr	NEWA
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MELOXICAMTABLET; ORALMELOXICAM

@ ROXANE

7.5MG

N77925 001 Jul 19, 2006 Feb DISC

@

15MG

N77925 002 Jul 19, 2006 Feb DISC

MEPIVACAINE HYDROCHLORIDEINJECTABLE; INJECTIONMEPIVACAINE HYDROCHLORIDE

>A>	AP	HOSPIRA INC	3%	N40806 001	Apr 28, 2008	Apr	NEWA
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MEPROBAMATETABLET; ORALMEPROBAMATE

AA		INVAGEN PHARMS	200MG	N40797 001	Feb 27, 2008	Feb	NEWA
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AA			400MG	N40797 002	Feb 27, 2008	Feb	NEWA
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>D>		@ LEINER	400MG	N14601 001		Apr	CAHN
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>A>		@ PVT FORM	400MG	N14601 001		Apr	CAHN
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AA	+	WATSON LABS	400MG	N83308 001		Feb	CTEC
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METAPROTERENOL SULFATESYRUP; ORALMETAPROTERENOL SULFATE

@ MORTON GROVE

10MG/5ML

N74702 001 Mar 24, 1997 Feb DISC

SYRUP; ORAL

METAPROTERENOL SULFATE

AA + SILARX 10MG/5ML N73632 001 Jul 22, 1992 Feb CRLD

METFORMIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

METFORMIN HYDROCHLORIDE

AB NEUROSCI INC 500MG N78321 001 Apr 17, 2008 Mar NEWA

AB 750MG N78321 002 Apr 17, 2008 Mar NEWA

METHSCOPOLAMINE BROMIDE

TABLET; ORAL

METHSCOPOLAMINE BROMIDE

>D> @ LEINER 2.5MG N80970 001 Apr CAHN

>A> @ PVT FORM 2.5MG N80970 001 Apr CAHN

PAMINE

AA + NYCOMED US 2.5MG N08848 001 Feb CAHN

PAMINE FORTE

AA + NYCOMED US 5MG N08848 002 Mar 25, 2003 Feb CAHN

>A> METHYLNALTREXONE BROMIDE

>A> SOLUTION; SUBCUTANEOUS

>A> RELISTOR

>A> + PROGENICS 12MG/0.6ML (12MG/0.6ML) N21964 001 Apr 24, 2008 Apr NEWA

METHYLPHENIDATE

FILM, EXTENDED RELEASE; TRANSDERMAL

DAYTRANA

>D> + SHIRE 10MG/9HR (1.1MG/HR) N21514 001 Apr 06, 2006 Apr CRLD

>A> 10MG/9HR (1.1MG/HR) N21514 001 Apr 06, 2006 Apr CRLD

>D> + 15MG/9HR (1.6MG/HR) N21514 002 Apr 06, 2006 Apr CRLD

>A> 15MG/9HR (1.6MG/HR) N21514 002 Apr 06, 2006 Apr CRLD

>D> + 20MG/9HR (2.2MG/HR) N21514 003 Apr 06, 2006 Apr CRLD

>A> 20MG/9HR (2.2MG/HR) N21514 003 Apr 06, 2006 Apr CRLD

METHYLTESTOSTERONE

TABLET; BUCCAL/SUBLINGUAL

METHYLTESTOSTERONE

>D> @ LEINER 5MG N83836 001 Apr CAHN

>A> @ PVT FORM 5MG N83836 001 Apr CAHN

TABLET; ORAL

METHYLTESTOSTERONE

>D> @ LEINER 5MG N80214 001 Apr CAHN

>D> @ 10MG N80214 002 Apr CAHN

>D> @ 25MG N80214 003 Apr CAHN

>A> @ PVT FORM 5MG N80214 001 Apr CAHN

>A> @ 10MG N80214 002 Apr CAHN

>A> @ 25MG N80214 003 Apr CAHN

METOCLOPRAMIDE HYDROCHLORIDE

SOLUTION; ORAL

METOCLOPRAMIDE HYDROCHLORIDE

AA + MORTON GROVE EQ 5MG BASE/5ML N74703 001 Oct 31, 1997 Feb CAHN

TABLET; ORAL

REGLAN

AB ALAVEN PHARM EQ 5MG BASE N17854 002 May 05, 1987 Mar CAHN

## TABLET; ORAL

## REGLAN

AB	+	ALAVEN PHARM	EQ 10MG BASE	N17854 001		Mar	CAHN
TABLET, ORALLY DISINTEGRATING; ORAL							
REGLAN ODT							
		@ ALAVEN PHARM	EQ 5MG BASE	N21793 001	Jun 10, 2005	Mar	CAHN
		@	EQ 10MG BASE	N21793 002	Jun 10, 2005	Mar	CAHN

METOPROLOL SUCCINATE

## TABLET, EXTENDED RELEASE; ORAL

## METOPROLOL SUCCINATE

AB		KV PHARM	EQ 25MG TARTRATE	N77779 001	Mar 20, 2008	Mar	NEWA
AB		SANDOZ	EQ 100MG TARTRATE	N76969 003	Mar 20, 2008	Mar	NEWA
AB			EQ 200MG TARTRATE	N76969 004	Mar 20, 2008	Mar	NEWA

METOPROLOL TARTRATE

## INJECTABLE; INJECTION

## METOPROLOL TARTRATE

>A>	AP	HOSPIRA	1MG/ML	N78085 001	Apr 29, 2008	Apr	NEWA
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METRONIDAZOLE

## INJECTABLE; INJECTION

## METRONIDAZOLE IN PLASTIC CONTAINER

AP		CLARIS LIFESCIENCES	500MG/100ML	N78084 001	Mar 31, 2008	Mar	NEWA
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MICONAZOLE NITRATE

## CREAM; TOPICAL

## MONISTAT-DERM

	+	ORTHONEUTROGENA	2%	N17494 001		Feb	CAHN
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MINOCYCLINE HYDROCHLORIDE

## CAPSULE; ORAL

## MINOCYCLINE HYDROCHLORIDE

AB		AUROBINDO PHARMA	EQ 50MG BASE	N65470 001	Mar 11, 2008	Feb	NEWA
AB			EQ 75MG BASE	N65470 002	Mar 11, 2008	Feb	NEWA
AB			EQ 100MG BASE	N65470 003	Mar 11, 2008	Feb	NEWA
>D>	AB	TEVA	EQ 100MG BASE	N63009 001	Mar 02, 1992	Apr	CRLD
>A>	AB	+	EQ 100MG BASE	N63009 001	Mar 02, 1992	Apr	CRLD
	AB		EQ 100MG BASE	N63009 001	Mar 02, 1992	Feb	CRLD

## TABLET; ORAL

## MINOCYCLINE HYDROCHLORIDE

AB		DR REDDYS LABS LTD	EQ 50MG BASE	N65436 001	Dec 26, 2007	Feb	CAHN
AB			EQ 75MG BASE	N65436 002	Dec 26, 2007	Feb	CAHN
AB			EQ 100MG BASE	N65436 003	Dec 26, 2007	Feb	CAHN

MINOXIDIL

## TABLET; ORAL

## LONITEN

	@	PHARMACIA AND UPJOHN	2.5MG	N18154 001		Jan	DISC
	@		10MG	N18154 003		Jan	DISC

## MINOXIDIL

AB	+	WATSON LABS	10MG	N71345 001	Mar 03, 1987	Mar	CRLD
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MITOXANTRONE HYDROCHLORIDE

INJECTABLE; INJECTION

MITOXANTRONE HYDROCHLORIDE

>A>	AP	DABUR ONCOLOGY PLC	EQ 20MG BASE/10ML(2MG/ML)	N78606 001	May 14, 2008	Apr	NEWA
>A>	AP		EQ 25MG BASE/12.5ML(2MG/ML)	N78606 002	May 14, 2008	Apr	NEWA
>A>	AP		EQ 30MG BASE/15ML (2MG/ML)	N78606 003	May 14, 2008	Apr	NEWA

MOMETASONE FUROATE

POWDER; INHALATION

ASMANEX TWISTHALER

SCHERING

0.11MG/INH

N21067 002 Feb 01, 2008 Feb NEWA

MORPHINE SULFATE

SOLUTION; ORAL

MORPHINE SULFATE

ROXANE

10MG/5ML

N22195 001 Mar 17, 2008 Mar NEWA

+

20MG/5ML

N22195 002 Mar 17, 2008 Mar NEWA

TABLET; ORAL

MORPHINE SULFATE

ROXANE

15MG

N22207 001 Mar 17, 2008 Mar NEWA

+

30MG

N22207 002 Mar 17, 2008 Mar NEWA

MUPIROCIN

OINTMENT; TOPICAL

CENTANY

BX

ORTHONEUTROGENA

2%

N50788 001 Dec 04, 2002 Feb CAHN

NABUMETONE

TABLET; ORAL

NABUMETONE

AB

INVAGEN PHARMS

500MG

N78671 001 Mar 07, 2008 Feb NEWA

AB

750MG

N78671 002 Mar 07, 2008 Feb NEWA

>A> NAPROXEN SODIUM; SUMATRIPTAN SUCCINATE

&gt;A&gt; TABLET; ORAL

&gt;A&gt; TREXIMET

&gt;A&gt; + POZEN 500MG;EQ 85MG BASE

N21926 001 Apr 15, 2008 Apr NEWA

NIACIN; SIMVASTATIN

TABLET, EXTENDED RELEASE; ORAL

SIMCOR

ABBOTT

500MG;20MG

N22078 001 Feb 15, 2008 Feb NEWA

750MG;20MG

N22078 002 Feb 15, 2008 Feb NEWA

+

1GM;20MG

N22078 003 Feb 15, 2008 Feb NEWA

NICARDIPINE HYDROCHLORIDE

CAPSULE; ORAL

CARDENE

&gt;A&gt; AB

EKR THERAP

20MG

N19488 001 Dec 21, 1988 Apr CAHN

&gt;A&gt; AB

+

30MG

N19488 002 Dec 21, 1988 Apr CAHN

&gt;D&gt; AB

PDL BIOPHARMA INC

20MG

N19488 001 Dec 21, 1988 Apr CAHN

&gt;D&gt; AB

+

30MG

N19488 002 Dec 21, 1988 Apr CAHN

NICARDIPINE HYDROCHLORIDE

AB

AMNEAL PHARM

20MG

N74928 001 Mar 19, 1998 Feb CAHN

AB

30MG

N74928 002 Mar 19, 1998 Feb CAHN

## CAPSULE, EXTENDED RELEASE; ORAL

## CARDENE SR

>A>	+	EKR THERAP	30MG	N20005 001	Feb 21, 1992	Apr	CAHN
>A>	+		45MG	N20005 002	Feb 21, 1992	Apr	CAHN
>A>	+		60MG	N20005 003	Feb 21, 1992	Apr	CAHN
>D>	+	PDL BIOPHARMA INC	30MG	N20005 001	Feb 21, 1992	Apr	CAHN
>D>	+		45MG	N20005 002	Feb 21, 1992	Apr	CAHN
>D>	+		60MG	N20005 003	Feb 21, 1992	Apr	CAHN

## INJECTABLE; INJECTION

## CARDENE

>A>	+	EKR THERAP	2.5MG/ML	N19734 001	Jan 30, 1992	Apr	CAHN
>D>	+	PDL BIOPHARMA INC	2.5MG/ML	N19734 001	Jan 30, 1992	Apr	CAHN

NIMODIPINE

## CAPSULE; ORAL

## NIMODIPINE

AB		BANNER PHARMACAPS	30MG	N76740 001	Jan 17, 2008	Jan	NEWA
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NISOLDIPINE

## TABLET, EXTENDED RELEASE; ORAL

## SULAR

	+	SCIELE PHARMA INC	8.5MG	N20356 008	Jan 02, 2008	Jan	NEWA
	+		17MG	N20356 007	Jan 02, 2008	Jan	NEWA
			25.5MG	N20356 006	Jan 02, 2008	Jan	NEWA
	+		34MG	N20356 005	Jan 02, 2008	Jan	NEWA

NITROFUZZONE

## OINTMENT; TOPICAL

## NITROFUZZONE

	@	TARO	0.2%	N86156 001		Jan	DISC
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NYSTATIN

## SUSPENSION; ORAL

## NILSTAT

>A>	AA	+	GLENMARK GENERICS	100,000 UNITS/ML	N50299 001		Apr	CAHN
>D>	AA	+	GLENMARK PHARMA	100,000 UNITS/ML	N50299 001		Apr	CAHN

## TABLET; ORAL

## NYSTATIN

AA	+	TEVA	500,000 UNITS	N62506 001	Jan 16, 1984	Jan	CRLD
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OCTREOTIDE ACETATE

## INJECTABLE; INJECTION

## OCTREOTIDE ACETATE

AP	+	BEDFORD	EQ 0.2MG BASE/ML	N76330 001	Apr 08, 2005	Jan	CRLD
AP	+		EQ 1MG BASE/ML	N76330 002	Apr 08, 2005	Jan	CRLD
AP		SUN PHARM INDS	EQ 0.05MG BASE/ML	N77329 001	Mar 04, 2008	Feb	NEWA
AP			EQ 0.1MG BASE/ML	N77329 002	Mar 04, 2008	Feb	NEWA
AP			EQ 0.2MG BASE/ML	N77330 001	Mar 04, 2008	Feb	NEWA
AP			EQ 0.5MG BASE/ML	N77329 003	Mar 04, 2008	Feb	NEWA
AP			EQ 1MG BASE/ML	N77331 001	Mar 04, 2008	Feb	NEWA

OFLOXACIN

## INJECTABLE; INJECTION

## OFLOXACIN

>D>							
>D>							
>D>	+	BEDFORD	40MG/ML	N75762 001	Jan 16, 2002	Apr	DISC
>A>	@		40MG/ML	N75762 001	Jan 16, 2002	Apr	DISC

## SOLUTION/DROPS; OPHTHALMIC

## OFLOXACIN

AT	AKORN	0.3%	N76407 001	Apr 15, 2008	Mar	NEWA
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## SOLUTION/DROPS; OTIC

## OFLOXACIN

AT	ALCON	0.3%	N78222 001	Mar 17, 2008	Mar	NEWA
AT	BAUSCH AND LOMB	0.3%	N76128 001	Mar 17, 2008	Mar	NEWA
AT	HI TECH PHARMA	0.3%	N76616 001	Mar 17, 2008	Mar	NEWA

OLOPATADINE HYDROCHLORIDE

## SOLUTION/DROPS; OPHTHALMIC

## PATADAY

>D>	+	ALCON	0.2%	N21545 001	Dec 22, 2004	Apr	CPOT
>A>	+		EQ 0.2% BASE	N21545 001	Dec 22, 2004	Apr	CPOT
>A>		SPRAY, METERED; NASAL					
>A>		PATANASE					
>A>	+	ALCON	0.665MG/SPRAY	N21861 001	Apr 15, 2008	Apr	NEWA

OMEPRAZOLE MAGNESIUM

## FOR SUSPENSION, DELAYED RELEASE; ORAL

## PRILOSEC

		ASTRAZENECA	EQ 2.5MG BASE/PACKET	N22056 001	Mar 20, 2008	Mar	NEWA
	+		EQ 10MG BASE/PACKET	N22056 002	Mar 20, 2008	Mar	NEWA

ONDANSETRON HYDROCHLORIDE

## INJECTABLE; INJECTION

## ONDANSETRON HYDROCHLORIDE

>A>	AP	AKORN STRIDES	EQ 2MG BASE/ML	N78257 001	Apr 23, 2008	Apr	NEWA
		ONDANSETRON HYDROCHLORIDE AND DEXTROSE IN PLASTIC CONTAINER					
	AP	CLARIS LIFESCIENCES	EQ 0.64MG BASE/ML	N78308 001	Mar 17, 2008	Mar	NEWA
		ONDANSETRON HYDROCHLORIDE PRESERVATIVE FREE					
>A>	AP	AKORN STRIDES	EQ 2MG BASE/ML	N78244 001	Apr 23, 2008	Apr	NEWA
	AP	TARO PHARMS IRELAND	EQ 2MG BASE/ML	N78014 001	Mar 21, 2008	Mar	NEWA

OXCARBAZEPINE

## TABLET; ORAL

## OXCARBAZEPINE

AB	APOTEX INC	150MG	N77747 001	Apr 09, 2008	Mar	NEWA
AB		300MG	N77747 002	Apr 09, 2008	Mar	NEWA
AB		600MG	N77747 003	Apr 09, 2008	Mar	NEWA

OXYCODONE HYDROCHLORIDE

## TABLET, EXTENDED RELEASE; ORAL

## OXYCODONE HYDROCHLORIDE

	@	IMPAX LABS	80MG	N76318 001	Sep 27, 2004	Feb	DISC
	@	IMPAX PHARMS	10MG	N76446 001	Dec 06, 2005	Feb	DISC
	@		20MG	N76446 002	Dec 06, 2005	Feb	DISC
	@		40MG	N76446 003	Dec 06, 2005	Feb	DISC
	@	TEVA	10MG	N76610 001	Dec 06, 2005	Feb	DISC
	@		20MG	N76610 002	Dec 06, 2005	Feb	DISC
	@		40MG	N76610 003	Dec 06, 2005	Feb	DISC
	@		80MG	N76168 001	Mar 23, 2004	Feb	DISC

## OXYCONTIN

		PURDUE PHARMA LP	10MG	N20553 001	Dec 12, 1995	Feb	CTEC
			15MG	N20553 006	Sep 18, 2006	Jan	CMFD
			20MG	N20553 002	Dec 12, 1995	Feb	CTEC

## TABLET, EXTENDED RELEASE; ORAL

## OXYCONTIN

	PURDUE PHARMA LP	30MG	N20553 007	Sep 18, 2006	Jan	CMFD
+		40MG	N20553 003	Dec 12, 1995	Feb	CTEC
		60MG	N20553 008	Sep 18, 2006	Jan	CMFD
		80MG	N20553 004	Jan 06, 1997	Feb	CTEC

OXYMORPHONE HYDROCHLORIDE

## TABLET, EXTENDED RELEASE; ORAL

## OPANA ER

	ENDO PHARMS	7.5MG	N21610 005	Feb 29, 2008	Feb	NEWA
		15MG	N21610 006	Feb 29, 2008	Feb	NEWA
		30MG	N21610 007	Feb 29, 2008	Feb	NEWA

OXYTETRACYCLINE HYDROCHLORIDE

## CAPSULE; ORAL

## TERRAMYCIN

	@ PFIZER	EQ 250MG BASE	N50286 002		Mar	DISC
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OXYTOCIN

## INJECTABLE; INJECTION

## OXYTOCIN

AP	+	APP PHARMS	100USP UNITS/10 ML (10USP UNITS/ML)	N18248 002		Jan	CFTG
AP	+	BAXTER HLTHCARE CORP	100USP UNITS/10ML (10USP UNITS/ML)	N18243 002	Jan 10, 2007	Mar	CDFR
AP		TEVA PARENTERAL	10USP UNITS/ML (10USP UNITS/ML)	N77453 001	Jan 24, 2008	Jan	NEWA
AP			100USP UNITS/10ML (10USP UNITS/ML)	N77453 002	Jan 24, 2008	Jan	NEWA
AP	+	BAXTER HLTHCARE CORP	100USP UNITS/10ML (10USP UNITS/ML)	N18243 002	Jan 10, 2007	Feb	NEWA

PACLITAXEL

## INJECTABLE; INJECTION

## PACLITAXEL

AP		PLIVA LACHEMA	6MG/ML	N77413 001	Mar 12, 2008	Feb	NEWA
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PALIPERIDONE

## TABLET, EXTENDED RELEASE; ORAL

## INVEGA

+	JANSSEN LP	6MG	N21999 002	Dec 19, 2006	Jan	CRLD
		9MG	N21999 003	Dec 19, 2006	Jan	CRLD

PALONOSETRON HYDROCHLORIDE

## INJECTABLE; INTRAVENOUS

## ALOXI

	HELSINN HLTHCARE	EQ 0.075MG BASE/1.5ML (EQ 0.05MG BASE/ML)	N21372 002	Feb 29, 2008	Feb	NEWA
+		EQ 0.25MG BASE/5ML (EQ 0.05MG BASE/ML)	N21372 001	Jul 25, 2003	Feb	CPOT

PAROXETINE HYDROCHLORIDE

## TABLET; ORAL

## PAROXETINE HYDROCHLORIDE

AB	MYLAN	EQ 10MG BASE	N78902 001	Mar 13, 2008	Mar	NEWA
AB		EQ 20MG BASE	N78902 002	Mar 13, 2008	Mar	NEWA

## TABLET; ORAL

## PAROXETINE HYDROCHLORIDE

AB	MYLAN	EQ 30MG BASE	N78902 003	Mar 13, 2008	Mar	NEWA
AB		EQ 40MG BASE	N78902 004	Mar 13, 2008	Mar	NEWA

PENICILLIN V POTASSIUM

## TABLET; ORAL

## PENICILLIN V POTASSIUM

>A>	AB	AUROBINDO PHARMA	EQ 250MG BASE	N65435 001	Apr 29, 2008	Apr	NEWA
>A>	AB		EQ 500MG BASE	N65435 002	Apr 29, 2008	Apr	NEWA

PHENDIMETRAZINE TARTRATE

## TABLET; ORAL

## DI-METREX

>D>	@	LEINER	35MG	N85698 001		Apr	CAHN
>A>	@	PVT FORM	35MG	N85698 001		Apr	CAHN

## PHENDIMETRAZINE TARTRATE

AA	ACTAVIS TOTOWA	35MG	N40762 001	Jan 28, 2008	Mar	CAHN	
AA	AMIDE PHARM	35MG	N40762 001	Jan 28, 2008	Jan	NEWA	
>D>	@	LEINER	35MG	N85199 001		Apr	CAHN
>D>	@		35MG	N85697 001		Apr	CAHN
>A>	@	PVT FORM	35MG	N85199 001		Apr	CAHN
>A>	@		35MG	N85697 001		Apr	CAHN

PHENTERMINE HYDROCHLORIDE

## CAPSULE; ORAL

## PHENTERMINE HYDROCHLORIDE

AA	KVK TECH	15MG	N40886 002	Mar 31, 2008	Mar	NEWA
AA		30MG	N40875 001	Mar 21, 2008	Mar	NEWA
AA		30MG	N40886 001	Mar 31, 2008	Mar	NEWA
>A>	AA	37.5MG	N40887 001	Apr 24, 2008	Apr	NEWA

## TABLET; ORAL

## PHENTERMINE HYDROCHLORIDE

AA	KVK TECH	37.5MG	N40876 001	Mar 31, 2008	Mar	NEWA
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PHENYTOIN SODIUM

## CAPSULE; ORAL

## EXTENDED PHENYTOIN SODIUM

AB	WOCKHARDT USA	100MG EXTENDED	N40732 001	Jan 30, 2008	Jan	NEWA
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## INJECTABLE; INJECTION

## PHENYTOIN SODIUM

AP	+	BAXTER	50MG/ML	N84307 001		Mar	CAHN
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POTASSIUM CHLORIDE

## TABLET, EXTENDED RELEASE; ORAL

## POTASSIUM CHLORIDE

AB	SCHERING	10MEQ	N19439 002	Jun 13, 1986	Jan	CTNA
AB	+	20MEQ	N19439 001	Jun 13, 1986	Jan	CTNA

PRAMIPEXOLE DIHYDROCHLORIDE

## TABLET; ORAL

## MIRAPEX

AB	BOEHRINGER INGELHEIM	0.125MG	N20667 001	Jul 01, 1997	Feb	CFTG
AB	+	0.25MG	N20667 002	Jul 01, 1997	Feb	CFTG
AB		0.5MG	N20667 006	Feb 12, 1998	Feb	CFTG
AB		1MG	N20667 003	Jul 01, 1997	Feb	CFTG



## TABLET; ORAL

## MIRAPEX

AB	BOEHRINGER INGELHEIM	1.5MG	N20667 005	Jul 01, 1997	Feb	CFTG
<u>PRAMIPEXOLE DIHYDROCHLORIDE</u>						
AB	BARR	0.125MG	N77724 001	Feb 19, 2008	Feb	NEWA
AB		0.25MG	N77724 002	Feb 19, 2008	Feb	NEWA
AB		0.5MG	N77724 003	Feb 19, 2008	Feb	NEWA
AB		1MG	N77724 004	Feb 19, 2008	Feb	NEWA
AB		1.5MG	N77724 005	Feb 19, 2008	Feb	NEWA

PRAVASTATIN SODIUM

## TABLET; ORAL

## PRAVASTATIN SODIUM

AB	LEK PHARMS DD	80MG	N77491 001	Feb 11, 2008	Jan	NEWA	
AB	TEVA PHARMS	80MG	N77793 001	Jan 15, 2008	Jan	NEWA	
>A>	AB	ZYDUS PHARMS USA	10MG	N77751 001	Apr 30, 2008	Apr	NEWA
>A>	AB		20MG	N77751 002	Apr 30, 2008	Apr	NEWA
>A>	AB		40MG	N77751 003	Apr 30, 2008	Apr	NEWA
>A>	AB		80MG	N77751 004	Apr 30, 2008	Apr	NEWA

PREDNISOLONE

## TABLET; ORAL

## PREDNISOLONE

>D>	@ LEINER	5MG	N80211 001		Apr	CAHN
>A>	@ PVT FORM	5MG	N80211 001		Apr	CAHN

PREDNISOLONE ACETATE

## SUSPENSION; ORAL

## FLO-PRED

	TARO	EQ 5MG BASE/5ML	N22067 001	Jan 17, 2008	Jan	NEWA
+		EQ 15MG BASE/5ML	N22067 002	Jan 17, 2008	Jan	NEWA

PREDNISOLONE SODIUM PHOSPHATE

## SOLUTION; ORAL

## PREDNISOLONE SODIUM PHOSPHATE

>D>	AA	PHARM ASSOC	EQ 10MG BASE/5ML	N78465 001	Mar 07, 2008	Apr	CRLD
>A>	+		EQ 10MG BASE/5ML	N78465 001	Mar 07, 2008	Apr	CRLD
	AA		EQ 10MG BASE/5ML	N78465 001	Mar 07, 2008	Feb	NEWA

PREDNISONE

## TABLET; ORAL

## PREDNISONE

>D>	@ LEINER	20MG	N85151 001		Apr	CAHN
>A>	@ PVT FORM	20MG	N85151 001		Apr	CAHN

PRIMIDONE

## TABLET; ORAL

## PRIMIDONE

>A>	AB	AMNEAL PHARM	50MG	N40866 001	Apr 23, 2008	Apr	NEWA
>A>	AB		250MG	N40866 002	Apr 23, 2008	Apr	NEWA
	AB	IMPAX LABS	50MG	N40717 001	Feb 12, 2008	Jan	NEWA
	AB		250MG	N40717 002	Feb 12, 2008	Jan	NEWA

PROCAINAMIDE HYDROCHLORIDE

## INJECTABLE; INJECTION

>D>		PRONESTYL					
>D>	AP	+	APOTHECON	100MG/ML	N07335 002		Apr DISC
>A>			@	100MG/ML	N07335 002		Apr DISC
>D>	AP	+		500MG/ML	N07335 005		Apr DISC
>A>			@	500MG/ML	N07335 005		Apr DISC
>D>			TABLET; ORAL				
>D>			PRONESTYL				
>D>			APOTHECON	250MG	N17371 001		Apr DISC
>A>			@	250MG	N17371 001		Apr DISC
>D>				375MG	N17371 002		Apr DISC
>A>			@	375MG	N17371 002		Apr DISC
>D>			+	500MG	N17371 003		Apr DISC
>A>			@	500MG	N17371 003		Apr DISC

PROCHLORPERAZINE EDISYLATE

## INJECTABLE; INJECTION

## PROCHLORPERAZINE EDISYLATE

	@	TEVA PARENTERAL	EQ 5MG BASE/ML	N40505 001	May 30, 2003	Jan	DISC
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PROMETHAZINE HYDROCHLORIDE

## INJECTABLE; INJECTION

## PROMETHAZINE HYDROCHLORIDE

>A>	AP		HIKMA FARMACEUTICA	25MG/ML	N40737 001	Apr 24, 2008	Apr	NEWA
>A>	AP			50MG/ML	N40737 002	Apr 24, 2008	Apr	NEWA
>D>	AP		HOSPIRA	50MG/ML	N83838 002		Apr	DISC
>A>			@	50MG/ML	N83838 002		Apr	DISC

## TABLET; ORAL

## PHENERGAN

	@	WYETH PHARMS INC	25MG	N07935 003			Feb	DISC
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## PROMETHAZINE HYDROCHLORIDE

	AB		ACTAVIS TOTOWA	12.5MG	N40673 001	Mar 05, 2008	Feb	NEWA
	AB			25MG	N40673 002	Mar 05, 2008	Feb	NEWA
	AB			50MG	N40673 003	Mar 05, 2008	Feb	NEWA
	AB		IMPAX LABS	12.5MG	N40724 001	Feb 12, 2008	Jan	NEWA
	AB			25MG	N40724 002	Feb 12, 2008	Jan	NEWA
>D>			@ LEINER	12.5MG	N83214 001		Apr	CAHN
>D>			@	25MG	N83658 001		Apr	CAHN
>A>			@ PVT FORM	12.5MG	N83214 001		Apr	CAHN
>A>			@	25MG	N83658 001		Apr	CAHN
>D>	BP		WATSON LABS	25MG	N83426 001		Apr	CTEC
>A>	AB			25MG	N83426 001		Apr	CTEC
>D>	BP			50MG	N83711 001		Apr	CTEC
>A>	AB			50MG	N83711 001		Apr	CTEC

PROPANTHELINE BROMIDE

## TABLET; ORAL

## PROPANTHELINE BROMIDE

>D>			@ LEINER	15MG	N80977 001		Apr	CAHN
>A>			@ PVT FORM	15MG	N80977 001		Apr	CAHN

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

PROPOXYPHENE HYDROCHLORIDE

>D>	@ LEINER	32MG	N83464 001	Apr	CAHN
>D>	@	65MG	N83113 001	Apr	CAHN
>A>	@ PVT FORM	32MG	N83464 001	Apr	CAHN
>A>	@	65MG	N83113 001	Apr	CAHN

PROPRANOLOL HYDROCHLORIDE

INJECTABLE; INJECTION

PROPRANOLOL HYDROCHLORIDE

AP	HIKMA FARMACEUTICA	1MG/ML	N77760 001	Jan 31, 2008	Jan	NEWA
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PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

TABLET; ORAL

ALLERFED

>D>	@ LEINER	60MG;2.5MG	N88860 001	Jan 31, 1985	Apr	CAHN
>A>	@ PVT FORM	60MG;2.5MG	N88860 001	Jan 31, 1985	Apr	CAHN

QUETIAPINE FUMARATE

TABLET, EXTENDED RELEASE; ORAL

SEROQUEL XR

>D>	ASTRAZENECA	EQ 50MG BASE	N22047 001	May 17, 2007	Apr	DISC
>A>	@	EQ 50MG BASE	N22047 001	May 17, 2007	Apr	DISC
	+	EQ 200MG BASE	N22047 002	May 17, 2007	Mar	CRLD
		EQ 400MG BASE	N22047 004	May 17, 2007	Mar	CRLD

RAMIPRIL

CAPSULE; ORAL

RAMIPRIL

>D>	AB	COBALT	1.25MG	N76549 001	Oct 24, 2005	Apr	CAHN
>D>	AB		2.5MG	N76549 002	Oct 24, 2005	Apr	CAHN
>D>	AB		5MG	N76549 003	Oct 24, 2005	Apr	CAHN
>D>	AB		10MG	N76549 004	Oct 24, 2005	Apr	CAHN
>A>	AB	COBALT LABS INC	1.25MG	N76549 001	Oct 24, 2005	Apr	CAHN
>A>	AB		2.5MG	N76549 002	Oct 24, 2005	Apr	CAHN
>A>	AB		5MG	N76549 003	Oct 24, 2005	Apr	CAHN
>A>	AB		10MG	N76549 004	Oct 24, 2005	Apr	CAHN

RAUWOLFIA SERPENTINA

TABLET; ORAL

RAUWOLFIA SERPENTINA

>D>	@ LEINER	50MG	N80583 001	Apr	CAHN
>D>	@	100MG	N80583 002	Apr	CAHN
>A>	@ PVT FORM	50MG	N80583 001	Apr	CAHN
>A>	@	100MG	N80583 002	Apr	CAHN

REGADENOSON

&gt;A&gt; INJECTABLE; INJECTION

&gt;A&gt; LEXISCAN

>A>	+	CV THERAP	0.4MG/5ML (0.08MG/ML)	N22161 001	Apr 10, 2008	Apr	NEWA
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RESERPINE

TABLET; ORAL

RESERPINE

>D>	@ LEINER	0.1MG	N86117 001	Apr	CAHN
>D>	@	0.25MG	N80582 001	Apr	CAHN
>D>	@	0.25MG	N85775 001	Apr	CAHN
>D>	@	1MG	N80582 002	Apr	CAHN
>A>	@ PVT FORM	0.1MG	N86117 001	Apr	CAHN
>A>	@	0.25MG	N80582 001	Apr	CAHN
>A>	@	0.25MG	N85775 001	Apr	CAHN
>A>	@	1MG	N80582 002	Apr	CAHN

RIBAVIRIN

TABLET; ORAL

RIBAVIRIN

>A>	ZYDUS PHARMS USA	500MG	N77094 004	Apr 18, 2008	Apr	NEWA
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RIFAMPIN

CAPSULE; ORAL

RIFAMPIN

AB	LANNETT	150MG	N65390 001	Mar 28, 2008	Mar	NEWA
AB		300MG	N65390 002	Mar 28, 2008	Mar	NEWA

RISEDRONATE SODIUM

TABLET; ORAL

ACTONEL

>A>	PROCTER AND GAMBLE	150MG	N20835 005	Apr 22, 2008	Apr	NEWA
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ROPINIROLE HYDROCHLORIDE

TABLET; ORAL

REQUIP

>D>	+ GLAXOSMITHKLINE	EQ 0.25MG BASE	N20658 001	Sep 19, 1997	Apr	CFTG
>A>	AB +	EQ 0.25MG BASE	N20658 001	Sep 19, 1997	Apr	CFTG
>D>		EQ 0.5MG BASE	N20658 002	Sep 19, 1997	Apr	CFTG
>A>	AB	EQ 0.5MG BASE	N20658 002	Sep 19, 1997	Apr	CFTG
>D>		EQ 1MG BASE	N20658 003	Sep 19, 1997	Apr	CFTG
>A>	AB	EQ 1MG BASE	N20658 003	Sep 19, 1997	Apr	CFTG
>D>		EQ 2MG BASE	N20658 004	Sep 19, 1997	Apr	CFTG
>A>	AB	EQ 2MG BASE	N20658 004	Sep 19, 1997	Apr	CFTG
>D>		EQ 3MG BASE	N20658 006	Jan 27, 1999	Apr	CFTG
>A>	AB	EQ 3MG BASE	N20658 006	Jan 27, 1999	Apr	CFTG
>D>		EQ 4MG BASE	N20658 007	Jan 27, 1999	Apr	CFTG
>A>	AB	EQ 4MG BASE	N20658 007	Jan 27, 1999	Apr	CFTG
>A>	ROPINIROLE HYDROCHLORIDE					
>A>	AB MYLAN	EQ 0.25MG BASE	N78881 001	May 05, 2008	Apr	NEWA
>A>	AB	EQ 0.5MG BASE	N78881 002	May 05, 2008	Apr	NEWA
>A>	AB	EQ 1MG BASE	N78881 003	May 05, 2008	Apr	NEWA
>A>	AB	EQ 2MG BASE	N78881 004	May 05, 2008	Apr	NEWA
>A>	AB	EQ 3MG BASE	N78881 005	May 05, 2008	Apr	NEWA
>A>	AB	EQ 4MG BASE	N78881 006	May 05, 2008	Apr	NEWA
>A>	AB PAR PHARM	EQ 0.25MG BASE	N78110 001	May 05, 2008	Apr	NEWA
>A>	AB	EQ 0.5MG BASE	N78110 002	May 05, 2008	Apr	NEWA
>A>	AB	EQ 1MG BASE	N78110 003	May 05, 2008	Apr	NEWA
>A>	AB	EQ 2MG BASE	N78110 004	May 05, 2008	Apr	NEWA
>A>	AB	EQ 3MG BASE	N78110 005	May 05, 2008	Apr	NEWA

TABLET; ORALROPINIROLE HYDROCHLORIDE

>A>	AB	PAR PHARM	EQ 4MG BASE	N78110 006	May 05, 2008	Apr	NEWA
>A>	AB	ROXANE	EQ 0.25MG BASE	N77852 001	May 05, 2008	Apr	NEWA
>A>	AB		EQ 0.5MG BASE	N77852 002	May 05, 2008	Apr	NEWA
>A>	AB		EQ 1MG BASE	N77852 003	May 05, 2008	Apr	NEWA
>A>	AB		EQ 2MG BASE	N77852 004	May 05, 2008	Apr	NEWA
>A>	AB		EQ 3MG BASE	N77852 005	May 05, 2008	Apr	NEWA
>A>	AB		EQ 4MG BASE	N77852 006	May 05, 2008	Apr	NEWA
>A>	AB	TEVA	EQ 0.25MG BASE	N77460 001	May 05, 2008	Apr	NEWA
>A>	AB		EQ 0.5MG BASE	N77460 002	May 05, 2008	Apr	NEWA
>A>	AB		EQ 1MG BASE	N77460 003	May 05, 2008	Apr	NEWA
>A>	AB		EQ 2MG BASE	N77460 004	May 05, 2008	Apr	NEWA
>A>	AB		EQ 3MG BASE	N77460 005	May 05, 2008	Apr	NEWA
>A>	AB		EQ 4MG BASE	N77460 006	May 05, 2008	Apr	NEWA

ROTIGOTINEFILM, EXTENDED RELEASE; TRANSDERMALNEUPRO

>D>		SCHWARZ BIOSCIENCES	2MG/24HR	N21829 001	May 09, 2007	Apr	DISC
>A>	@		2MG/24HR	N21829 001	May 09, 2007	Apr	DISC
>D>			4MG/24HR	N21829 002	May 09, 2007	Apr	DISC
>A>	@		4MG/24HR	N21829 002	May 09, 2007	Apr	DISC
>D>	+		6MG/24HR	N21829 003	May 09, 2007	Apr	DISC
>A>	@		6MG/24HR	N21829 003	May 09, 2007	Apr	DISC

SERTACONAZOLE NITRATECREAM; TOPICALERTACZO

+		ORTHONEUTROGENA	2%	N21385 001	Dec 10, 2003	Feb	CAHN
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SERTRALINE HYDROCHLORIDETABLET; ORALSERTRALINE HYDROCHLORIDE

AB		MATRIX LABS LTD	EQ 25MG BASE	N78626 001	Jan 31, 2008	Jan	NEWA
AB			EQ 50MG BASE	N78626 002	Jan 31, 2008	Jan	NEWA
AB			EQ 100MG BASE	N78626 003	Jan 31, 2008	Jan	NEWA

SIMVASTATINTABLET; ORALSIMVASTATIN

AB		ACCORD HLTHCARE	10MG	N78155 002	Feb 26, 2008	Feb	NEWA
AB			20MG	N78155 003	Feb 26, 2008	Feb	NEWA
AB			40MG	N78155 004	Feb 26, 2008	Feb	NEWA
AB			80MG	N78155 001	Feb 26, 2008	Feb	NEWA

SODIUM IODIDE, I-131CAPSULE; ORALHICON

		DRAXIMAGE	100uCi	N21305 004	Nov 18, 2004	Feb	CTNA
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SOLUTION; ORALHICON

+		DRAXIMAGE	1-250mCi/0.25ML	N21305 002	Jan 24, 2003	Feb	CTNA
+			1-500mCi/0.5ML	N21305 003	Jan 24, 2003	Feb	CTNA

SODIUM LACTATE

INJECTABLE; INJECTION

SODIUM LACTATE 0.167 MOLAR IN PLASTIC CONTAINER

>D>	AP	HOSPIRA	1.87GM/100ML	N18249 001		Apr	DISC
>A>		@	1.87GM/100ML	N18249 001		Apr	DISC

SOMATROPIN RECOMBINANT

INJECTABLE; INJECTION

ACCRETROPIN

	+	CANGENE	5MG/ML (5MG/ML)	N21538 001	Jan 23, 2008	Jan	NEWA
BX		NORDITROPIN NOVO NORDISK INC	5MG/1.5ML	N21148 001	Jun 20, 2000	Jan	CTEC
BX		NORDITROPIN NORDIFLEX NOVO NORDISK INC	5MG/1.5ML	N21148 004	Oct 01, 2004	Jan	CTEC
	+	NUTROPIN AQ GENENTECH	5MG/2ML (2.5MG/ML)	N20522 003	Jan 03, 2008	Jan	NEWA
	+		10MG/2ML (5MG/ML)	N20522 001	Dec 29, 1995	Jan	CPOT
	+		20MG/2ML (10MG/ML)	N20522 004	Jan 03, 2008	Jan	NEWA
	+	NUTROPIN AQ PEN GENENTECH	10MG/2ML (5MG/ML)	N20522 002	Apr 22, 2002	Jan	CPOT
BX		OMNITROPE SANDOZ	5MG/1.5ML	N21426 003	Jan 16, 2008	Jan	NEWA
BX	+	TEV-TROPIN FERRING	5MG/VIAL	N19774 002	Jan 04, 2002	Jan	CPOT
		INJECTABLE; SUBCUTANEOUS SEROSTIM LQ					
	+	EMD SERONO	6MG/0.5ML (6MG/0.5ML)	N20604 005	Feb 11, 2005	Feb	CMFD

SOTALOL HYDROCHLORIDE

TABLET; ORAL

SOTALOL HYDROCHLORIDE

AB2		AMNEAL PHARM	80MG	N77070 001	Nov 04, 2005	Feb	CAHN
AB2			120MG	N77070 002	Nov 04, 2005	Feb	CAHN
AB2			160MG	N77070 003	Nov 04, 2005	Feb	CAHN
		@ MUTUAL PHARM	80MG	N76576 001	Apr 08, 2004	Mar	DISC
		@	120MG	N76576 002	Apr 08, 2004	Mar	DISC
		@	160MG	N76576 003	Apr 08, 2004	Mar	DISC

SPIRONOLACTONE

TABLET; ORAL

SPIRONOLACTONE

	@	MUTUAL PHARM	25MG	N87265 001		Mar	DISC
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SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION

SULFAMETHOXAZOLE AND TRIMETHOPRIM

	@	BAXTER HLTHCARE	80MG/ML; 16MG/ML	N70628 001	Dec 29, 1987	Mar	DISC
	@	HOSPIRA	80MG/ML; 16MG/ML	N73199 001	Sep 11, 1992	Mar	DISC
	+	TEVA PARENTERAL	80MG/ML; 16MG/ML	N73303 001	Oct 31, 1991	Mar	CRLD

SULFASALAZINE

TABLET; ORAL

SULFASALAZINE

	@	MUTUAL PHARM	500MG	N89590 001	Oct 19, 1987	Mar	DISC
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TADALAFIL

TABLET; ORAL

CIALIS

LILLY 2.5MG N21368 004 Jan 07, 2008 Jan NEWA

TECHNETIUM TC-99M MEBROFENIN KIT

INJECTABLE; INJECTION

CHOLETEC

AP + BRACCO N/A N18963 001 Jan 21, 1987 Jan CFTG

TECHNETIUM TC-99M MEBROFENIN

AP CIS N/A N78242 001 Jan 29, 2008 Jan NEWA

TECHNETIUM TC-99M MEDRONATE KIT

INJECTABLE; INJECTION

DRAXIMAGE MDP-25

AP + DRAXIMAGE N/A N18035 002 Feb 27, 2004 Mar CTEC

TERAZOSIN HYDROCHLORIDE

CAPSULE; ORAL

TERAZOSIN HYDROCHLORIDE

@ MYLAN TECHNOLOGIES EQ 1MG BASE N75384 001 Dec 01, 2000 Feb DISC

@ EQ 2MG BASE N75384 002 Dec 01, 2000 Feb DISC

@ EQ 5MG BASE N75384 003 Dec 01, 2000 Feb DISC

@ EQ 10MG BASE N75384 004 Dec 01, 2000 Feb DISC

TESTOLACTONE

TABLET; ORAL

TESLAC

@ BRISTOL MYERS SQUIBB 50MG N16118 001 Feb DISC

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL

TETRACYCLINE HYDROCHLORIDE

&gt;D&gt; @ LEINER 250MG N62686 001 Jul 24, 1986 Apr CAHN

&gt;D&gt; @ 500MG N62686 002 Jul 24, 1986 Apr CAHN

&gt;A&gt; @ PVT FORM 250MG N62686 001 Jul 24, 1986 Apr CAHN

&gt;A&gt; @ 500MG N62686 002 Jul 24, 1986 Apr CAHN

THALLOUS CHLORIDE, TL-201

INJECTABLE; INTRAVENOUS

THALLOUS CHLORIDE TL 201

&gt;A&gt; AP MALLINCKRODT 2mCi/ML N77698 001 Nov 09, 2006 Apr CAHN

&gt;D&gt; AP TCI MEDCL 2mCi/ML N77698 001 Nov 09, 2006 Apr CAHN

THEOPHYLLINE

TABLET, EXTENDED RELEASE; ORAL

UNIPHYL

AB PURDUE PHARM PRODS 400MG N87571 001 Sep 01, 1982 Feb CAHN

AB + 600MG N40086 001 Apr 15, 1996 Feb CAHN

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL

THIORIDAZINE HYDROCHLORIDE

@ MUTUAL PHARM 50MG N88370 001 Nov 18, 1983 Feb DISC

TIMOLOL MALEATE

SOLUTION/DROPS; OPHTHALMIC

TIMOLOL MALEATE

>A>	AT	FDC LTD	EQ 0.25% BASE	N77259 001	Apr 30, 2008	Apr	NEWA
>A>	AT		EQ 0.5% BASE	N77259 002	Apr 30, 2008	Apr	NEWA

TIROFIBAN HYDROCHLORIDE

INJECTABLE; INJECTION

AGGRASTAT

@ MEDICURE

EQ 12.5MG BASE/50ML (EQ 0.25MG  
BASE/ML)

N20912 001 May 14, 1998 Mar DISC

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION

TOBRAMYCIN

AP		APP PHARMS	EQ 1.2GM BASE/VIAL	N50789 001	Jul 13, 2004	Feb	CTEC
AP	+	X GEN PHARMS	EQ 1.2GM BASE/VIAL	N65013 001	Aug 17, 2001	Feb	CTEC

TOBRAMYCIN SULFATE

AP		ABRAXIS PHARM	EQ 10MG BASE/ML	N65122 001	Nov 29, 2002	Mar	CTNA
AP	+		EQ 40MG BASE/ML	N65122 002	Nov 29, 2002	Mar	CTNA
AP		AKORN STRIDES	EQ 40MG BASE/ML	N65407 001	Mar 11, 2008	Feb	NEWA
AP		APP PHARMS	EQ 1.2GM BASE/VIAL	N50789 001	Jul 13, 2004	Mar	CTNA
AP	+	X GEN PHARMS	EQ 1.2GM BASE/VIAL	N65013 001	Aug 17, 2001	Mar	CTNA

TOBRAMYCIN SULFATE (PHARMACY BULK)

AP		ABRAXIS PHARM	EQ 40MG BASE/ML	N65120 001	Nov 29, 2002	Mar	CTNA
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TORSEMIDE

TABLET; ORAL

TORSEMIDE

AB		SUN PHARM INDS	5MG	N78478 001	Feb 26, 2008	Feb	NEWA
AB			10MG	N78478 002	Feb 26, 2008	Feb	NEWA
AB			20MG	N78478 003	Feb 26, 2008	Feb	NEWA
AB			100MG	N78478 004	Feb 26, 2008	Feb	NEWA

TRANDOLAPRIL

TABLET; ORAL

TRANDOLAPRIL

>A>	AB	MYLAN	1MG	N78346 001	Apr 28, 2008	Apr	NEWA
>A>	AB		2MG	N78346 002	Apr 28, 2008	Apr	NEWA
>A>	AB		4MG	N78346 003	Apr 28, 2008	Apr	NEWA

VALPROIC ACID

SYRUP; ORAL

VALPROIC ACID

AA		MORTON GROVE	250MG/5ML	N70868 001	Jul 01, 1986	Feb	CTNA
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VARDENAFIL HYDROCHLORIDE

TABLET; ORAL

LEVITRA

BAYER HLTHCARE

			2.5MG	N21400 003	Aug 19, 2003	Jan	CAHN
			5MG	N21400 001	Aug 19, 2003	Jan	CAHN
			10MG	N21400 002	Aug 19, 2003	Jan	CAHN
	+		20MG	N21400 004	Aug 19, 2003	Jan	CAHN



VECURONIUM BROMIDE

INJECTABLE; INJECTION  
VECURONIUM BROMIDE

>D>	+	HOSPIRA	4MG/VIAL	N75558 001	Sep 11, 2001	Apr	DISC
>A>	@		4MG/VIAL	N75558 001	Sep 11, 2001	Apr	DISC

VINORELBINE TARTRATE

INJECTABLE; INJECTION  
VINORELBINE TARTRATE

AP		EBEWE PHARMA	EQ 10MG BASE/ML	N78408 001	Feb 13, 2008	Jan	NEWA
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ZIDOVUDINE

TABLET; ORAL  
ZIDOVUDINE

>A>	AB	HETERO DRUGS LTD	300MG	N90092 001	Apr 25, 2008	Apr	NEWA
	AB	MATRIX LABS LTD	300MG	N78922 001	Feb 14, 2008	Jan	NEWA

ZILEUTON

TABLET; ORAL  
ZYFLO

	@	CRITICAL	600MG	N20471 003	Dec 09, 1996	Feb	DISC
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ZOLPIDEM TARTRATE

TABLET; ORAL  
ZOLPIDEM TARTRATE

>A>	AB	HIKMA	5MG	N78129 001	Apr 30, 2008	Apr	NEWA
>A>	AB		10MG	N78129 002	Apr 30, 2008	Apr	NEWA

OTC DRUG PRODUCT LIST - 28TH EDITION

OTC DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2008

2-1

AVOBENZONE; ECAMSULE; OCTOCRYLENE; TITANIUM DIOXIDE

CREAM; TOPICAL

ANTHELIOS 40

+ LOREAL USA 2%;3%;10%;5% N22009 001 Mar 31, 2008 Mar NEWA

CALCIUM CARBONATE; FAMOTIDINE; MAGNESIUM HYDROXIDE

TABLET, CHEWABLE; ORAL

CALCIUM CARBONATE, FAMOTIDINE AND MAGNESIUM HYDROXIDE

PERRIGO R AND D 800MG;10MG;165MG N77355 001 Feb 06, 2008 Jan NEWA

CETIRIZINE HYDROCHLORIDE

SYRUP; ORAL

CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY

>A> ACTAVIS MID ATLANTIC 5MG/5ML N90378 002 May 09, 2008 Apr NEWA  
 >A> APOTEX 5MG/5ML N90188 002 Apr 22, 2008 Apr NEWA  
 PERRIGO R AND D 5MG/5ML N90254 002 Apr 09, 2008 Mar NEWA  
 >A> RANBAXY 5MG/5ML N90183 002 Apr 24, 2008 Apr NEWA  
 >A> TARO 5MG/5ML N90182 002 Apr 22, 2008 Apr NEWA

CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF

>A> ACTAVIS MID ATLANTIC 5MG/5ML N90378 001 May 09, 2008 Apr NEWA  
 >A> APOTEX 5MG/5ML N90188 001 Apr 22, 2008 Apr NEWA  
 PERRIGO R AND D 5MG/5ML N90254 001 Apr 09, 2008 Mar NEWA  
 >A> RANBAXY 5MG/5ML N90183 001 Apr 24, 2008 Apr NEWA  
 >A> TARO 5MG/5ML N90182 001 Apr 22, 2008 Apr NEWA

CHILDREN'S ZYRTEC ALLERGY

+ MCNEIL CONSUMER 5MG/5ML N22155 002 Nov 16, 2007 Mar CPOT  
 + 1MG/ML N22155 002 Nov 16, 2007 Jan CAHN

CHILDREN'S ZYRTEC HIVES RELIEF

+ MCNEIL CONSUMER 5MG/5ML N22155 001 Nov 16, 2007 Mar CPOT  
 + 1MG/ML N22155 001 Nov 16, 2007 Jan CAHN

TABLET, CHEWABLE; ORAL

CETIRIZINE HYDROCHLORIDE ALLERGY

SANDOZ 5MG N78692 001 Feb 14, 2008 Jan NEWA  
 10MG N78692 002 Feb 14, 2008 Jan NEWA

TABLET; ORAL

CETIRIZINE HYDROCHLORIDE ALLERGY

>A> CONTRACT PHARMA 5MG N76047 001 Dec 27, 2007 Apr CAHN  
 >A> 10MG N76047 002 Dec 27, 2007 Apr CAHN  
 DR REDDYS LABS LTD 5MG N78343 004 Jan 15, 2008 Jan NEWA  
 10MG N78343 003 Jan 15, 2008 Jan NEWA  
 >D> PAR PHARM 5MG N76047 001 Dec 27, 2007 Apr CAHN  
 >D> 10MG N76047 002 Dec 27, 2007 Apr CAHN

CETIRIZINE HYDROCHLORIDE HIVES

>A> CONTRACT PHARMA 5MG N76047 003 Dec 27, 2007 Apr CAHN  
 >A> 10MG N76047 004 Dec 27, 2007 Apr CAHN  
 DR REDDYS LABS LTD 5MG N78343 001 Jan 15, 2008 Jan NEWA  
 10MG N78343 002 Jan 15, 2008 Jan NEWA  
 >D> PAR PHARM 5MG N76047 003 Dec 27, 2007 Apr CAHN  
 >D> 10MG N76047 004 Dec 27, 2007 Apr CAHN

ZYRTEC ALLERGY

MCNEIL CONSUMER 5MG N19835 003 Nov 16, 2007 Jan CAHN  
 + 10MG N19835 004 Nov 16, 2007 Jan CAHN

## TABLET; ORAL

## ZYRTEC HIVES RELIEF

	MCNEIL CONSUMER	5MG	N19835 005	Nov 16, 2007	Jan	CAHN
+		10MG	N19835 006	Nov 16, 2007	Jan	CAHN

CETIRIZINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

## TABLET, EXTENDED RELEASE; ORAL

## CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE

	SANDOZ	5MG;120MG	N77991 001	Mar 05, 2008	Feb	NEWA
	TEVA PHARMS	5MG;120MG	N77170 001	Feb 25, 2008	Feb	NEWA
+	ZYRTEC-D 12 HOUR MCNEIL	5MG;120MG	N21150 002	Nov 09, 2007	Jan	CAHN

LOPERAMIDE HYDROCHLORIDE; SIMETHICONE

## TABLET, CHEWABLE; ORAL

>D>	IMODIUM ADVANCED					
>D>	+ MCNEIL	2MG;125MG	N20606 001	Jun 26, 1996	Apr	CTNA
>A>	IMODIUM MULTI-SYMPTOM RELIEF					
>A>	+ MCNEIL	2MG;125MG	N20606 001	Jun 26, 1996	Apr	CTNA

## TABLET; ORAL

>D>	IMODIUM ADVANCED					
>D>	+ MCNEIL CONS	2MG;125MG	N21140 001	Nov 30, 2000	Apr	CTNA
>A>	IMODIUM MULTI-SYMPTOM RELIEF					
>A>	+ MCNEIL CONS	2MG;125MG	N21140 001	Nov 30, 2000	Apr	CTNA

MENTHOL; METHYL SALICYLATE

## PATCH; TOPICAL

## SALONPAS

+	HISAMITSU	3%;10%	N22029 001	Feb 20, 2008	Feb	NEWA
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MINOXIDIL

## SOLUTION; TOPICAL

## MINOXIDIL (FOR WOMEN)

	HI TECH PHARMA	2%	N74731 002	May 11, 2005	Mar	NEWA
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NICOTINE POLACRILEX

## GUM, CHEWING; BUCCAL

## NICOTINE POLACRILEX

>A>	PERRIGO R AND D	EQ 2MG BASE	N78967 001	Apr 23, 2008	Apr	NEWA
>A>		EQ 4MG BASE	N78968 001	Apr 23, 2008	Apr	NEWA

POTASSIUM IODIDE

## TABLET; ORAL

## THYROSAFE

+	RECIP	65MG	N76350 001	Sep 10, 2002	Jan	CAHN
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**DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT  
ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST**

**CUMULATIVE SUPPLEMENT NUMBER 04 APRIL 2008**

NO APRIL 2008 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 2008 ADDITIONS

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT - 2008

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>ADEFOVIR DIPIVOXIL - HEPSERA</u>						
021449 001					NPP	Dec 19, 2010
<u>ALENDRONATE SODIUM - ALENDRONATE SODIUM</u>						
075710 001					PC	Aug 04, 2008
<u>ALENDRONATE SODIUM - ALENDRONATE SODIUM</u>						
075710 002					PC	Aug 04, 2008
<u>ALENDRONATE SODIUM - ALENDRONATE SODIUM</u>						
075710 003					PC	Aug 04, 2008
<u>ALENDRONATE SODIUM - ALENDRONATE SODIUM</u>						
075710 004					PC	Aug 04, 2008
<u>ALENDRONATE SODIUM - ALENDRONATE SODIUM</u>						
075710 005					PC	Aug 04, 2008
<u>ALENDRONATE SODIUM - ALENDRONATE SODIUM</u>						
076184 001					PC	Aug 04, 2008
<u>ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE - TEKTURN HCT</u>						
022107 001	>A> 5559111	Apr 04, 2015	DS DP U-3		NCE NC	Mar 05, 2012 Jan 18, 2011
<u>ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE - TEKTURN HCT</u>						
022107 002	>A> 5559111	Apr 04, 2015	DS DP U-3		NCE NC	Mar 05, 2012 Jan 18, 2011
<u>ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE - TEKTURN HCT</u>						
022107 003	>A> 5559111	Apr 04, 2015	DS DP U-3		NCE NC	Mar 05, 2012 Jan 18, 2011
<u>ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE - TEKTURN HCT</u>						
022107 004	>A> 5559111	Apr 04, 2015	DS DP U-3		NCE NC	Mar 05, 2012 Jan 18, 2011
<u>ALOSETRON HYDROCHLORIDE - LOTRONEX</u>						
021107 001					D-113	Apr 01, 2011
<u>ALOSETRON HYDROCHLORIDE - LOTRONEX</u>						
021107 002					D-113	Apr 01, 2011
<u>AMIFOSTINE - AMIFOSTINE</u>						
077126 001					>A> PC	Sep 23, 2008
<u>APREPITANT - EMEND</u>						
021549 001	5719147	Apr 17, 2015	DS DP U-853			
	7214692	Sep 18, 2012	U-853			
<u>APREPITANT - EMEND</u>						
021549 002	7214692	Sep 18, 2012	U-853			
<u>APREPITANT - EMEND</u>						
021549 003	7214692	Sep 18, 2012	U-853			
<u>ARFORMOTEROL TARTRATE - BROVANA</u>						
021912 001	6040344	Nov 12, 2016	DS			
	6472563	Nov 09, 2021	DS			
	6720453	Nov 09, 2021	DS			
	7145036	Nov 09, 2021	DS			

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT - 2008

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>ARIPIPRAZOLE - ABILIFY</u>						
021436	001				D-110 I-555 PED PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>						
021436	002				D-110 I-555 PED PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>						
021436	003				D-110 I-555 PED PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>						
021436	004				D-110 I-555 PED PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>						
021436	005				D-110 I-555 PED PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>						
021436	006				D-110 I-555 PED PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>						
021713	001				D-110 I-555 PED PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>						
021729	002				D-110 I-555 PED PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>						
021729	003				D-110 I-555 PED PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>						
021729	004				D-110 I-555 PED PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>						
021729	005				D-110 I-555 PED PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011



## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT - 2008

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>ARIPIPRAZOLE - ABILIFY</u>						
021866	001				D-110 I-555 PED PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ATAZANAVIR SULFATE - REYATAZ</u>						
021567	001				NPP	Mar 25, 2011
<u>ATAZANAVIR SULFATE - REYATAZ</u>						
021567	002				NPP	Mar 25, 2011
<u>ATAZANAVIR SULFATE - REYATAZ</u>						
021567	003				NPP	Mar 25, 2011
<u>ATAZANAVIR SULFATE - REYATAZ</u>						
021567	004				NPP	Mar 25, 2011
<u>AVOBENZONE; ECAMSULE; OCTOCRYLENE; TITANIUM DIOXIDE - ANTHELIOS 40</u>						
022009	001				NP NC	Mar 31, 2011 Oct 05, 2009
<u>BENDAMUSTINE HYDROCHLORIDE - TREANDA</u>						
022249	001				NCE ODE	Mar 20, 2013 Mar 20, 2015
<u>BETAMETHASONE DIPROPIONATE; CALCIPOTRIENE HYDRATE - TACLONEX</u>						
021852	001	RE39706	Jun 09, 2015	DS DP		
<u>BRIMONIDINE TARTRATE; TIMOLOL MALEATE - COMBIGAN</u>						
021398	001	7030149	Apr 19, 2022		U-849	
		7320976	Apr 19, 2022		U-849	
		7323463	Jan 19, 2023	DP		
<u>BUDESONIDE - RHINOCORT</u>						
020746	001	6291445	Apr 29, 2017		Y	
		6686346	Apr 29, 2017	DP	U-557	Y
		6986904	Apr 29, 2017	DP	U-699	Y
<u>BUPROPION HYDROCHLORIDE - WELLBUTRIN XL</u>						
021515	001	6143327	Oct 30, 2018		Y	
<u>CALCIPOTRIENE - DOVONEX</u>						
020554	001	RE39706	Jun 09, 2015	DS DP		
<u>CALCIPOTRIENE - DOVONEX</u>						
020611	001	RE39706	Jun 09, 2015	DS DP		
<u>CARVEDILOL - COREG</u>						
020297	001	RE40000	Jun 07, 2015		U-233	
		RE40000*PED	Dec 07, 2015			
<u>CARVEDILOL - COREG</u>						
020297	002	RE40000	Jun 07, 2015		U-233	
		RE40000*PED	Dec 07, 2015			
<u>CARVEDILOL - COREG</u>						
020297	003	RE40000	Jun 07, 2015		U-233	
		RE40000*PED	Dec 07, 2015			

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT - 2008

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>CARVEDILOL - COREG</u>						
020297 004	RE40000	Jun 07, 2015	U-233			
	RE40000*PED	Dec 07, 2015				
<u>CARVEDILOL PHOSPHATE - COREG CR</u>						
022012 001	RE40000	Jun 07, 2015	U-777			
	RE40000*PED	Dec 07, 2015				
<u>CARVEDILOL PHOSPHATE - COREG CR</u>						
022012 002	RE40000	Jun 07, 2015	U-777			
	RE40000*PED	Dec 07, 2015				
<u>CARVEDILOL PHOSPHATE - COREG CR</u>						
022012 003	RE40000	Jun 07, 2015	U-777			
	RE40000*PED	Dec 07, 2015				
<u>CARVEDILOL PHOSPHATE - COREG CR</u>						
022012 004	RE40000	Jun 07, 2015	U-777			
	RE40000*PED	Dec 07, 2015				
<u>CASPOFUNGIN ACETATE - CANCIDAS</u>						
021227 001	5378804	Mar 16, 2013	DS			
	5378804*PED	Sep 16, 2013				
	5514650	Jan 26, 2015	DP U-607			
	5514650*PED	Jul 26, 2015				
	5792746	Mar 16, 2013	DS DP U-607			
	5792746*PED	Sep 16, 2013				
	5952300	Mar 28, 2017	DP			
	5952300*PED	Sep 28, 2017				
	6136783	Mar 28, 2017	U-607			
	6136783*PED	Sep 28, 2017				
<u>CASPOFUNGIN ACETATE - CANCIDAS</u>						
021227 002	5378804	Mar 16, 2013	DS			
	5378804*PED	Sep 16, 2013				
	5514650	Jan 26, 2015	DP U-607			
	5514650*PED	Jul 26, 2015				
	5792746	Mar 16, 2013	DS DP U-607			
	5792746*PED	Sep 16, 2013				
	5952300	Mar 28, 2017	DP			
	5952300*PED	Sep 28, 2017				
	6136783	Mar 28, 2017	U-607			
	6136783*PED	Sep 28, 2017				

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT - 2008

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>CICLESONIDE - ALVESCO</u>						
021658 002	5482934	Jan 09, 2013	DS DP U-645			
	5482934	Jan 09, 2013	DS DP U-675			
	5482934	Jan 09, 2013	DS DP U-738			
	5482934	Jan 09, 2013	DS DP U-754			
	5482934	Jan 09, 2013	DS DP U-841			
	5482934	Jan 09, 2013	DS DP U-228			
	5605674	Feb 25, 2014	DP			
	5683677	Nov 04, 2014	DP			
	5695743	Jul 06, 2010	DP U-675			
	5695743	Jul 06, 2010	DP U-645			
	5695743	Jul 06, 2010	DP U-738			
	5695743	Jul 06, 2010	DP U-754			
	5695743	Jul 06, 2010	DP U-841			
	5695743	Jul 06, 2010	DP U-228			
	5775321	Jul 07, 2015	DP			
	6006745	Dec 28, 2016	DP			
	6036942	Apr 30, 2013	DP			
	6120752	May 13, 2018	DP			
	6264923	May 13, 2013	DP			
<u>CICLESONIDE - ALVESCO</u>						
021658 003	5482934	Jan 09, 2013	DS DP U-645			
	5482934	Jan 09, 2013	DS DP U-675			
	5482934	Jan 09, 2013	DS DP U-738			
	5482934	Jan 09, 2013	DS DP U-754			
	5482934	Jan 09, 2013	DS DP U-841			
	5482934	Jan 09, 2013	DS DP U-228			
	5605674	Feb 25, 2014	DP			
	5683677	Nov 04, 2014	DP			
	5695743	Jul 06, 2010	DP U-675			
	5695743	Jul 06, 2010	DP U-645			
	5695743	Jul 06, 2010	DP U-738			
	5695743	Jul 06, 2010	DP U-754			
	5695743	Jul 06, 2010	DP U-841			
	5695743	Jul 06, 2010	DP U-228			
	5775321	Jul 07, 2015	DP			
	6006745	Dec 28, 2016	DP			
	6036942	Apr 30, 2013	DP			
	6120752	May 13, 2018	DP			
	6264923	May 13, 2013	DP			
<u>CLOBETASOL PROPIONATE - CLOBETASOL PROPIONATE</u>						
077763 001					PC	Sep 16, 2008
<u>CLOFARABINE - CLOLAR</u>						
021673 001	5661136	Jan 14, 2018	U-626			
<u>CLOPIDOGREL BISULFATE - PLAVIX</u>						
020839 001	5576328	Jan 31, 2014	U-432	Y		
<u>CLOZAPINE - FAZACLO ODT</u>						
021590 001	>A> 6106861	Dec 05, 2017	DP			

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<u>CLOZAPINE - FAZACLO ODT</u>						
021590 002	>A> 6106861	Dec 05, 2017	DP			
<u>CLOZAPINE - FAZACLO ODT</u>						
021590 003	>A> 6106861	Dec 05, 2017	DP			
<u>CLOZAPINE - FAZACLO ODT</u>						
021590 004	>A> 6106861	Dec 05, 2017	DP			
<u>COLESEVELAM HYDROCHLORIDE - WELCHOL</u>						
021176 001	5919832	Apr 29, 2014	DS		I-553	Jan 18, 2011
	6066678	Apr 29, 2014	DS	U-323		
	6433026	Apr 29, 2014	DS			
	6784254	Apr 29, 2014	DS DP			
	7229613	Apr 17, 2022		U-851		
<u>CONIVAPTAN HYDROCHLORIDE - VAPRISOL</u>						
021697 001	>A> 5723606	Dec 15, 2019	DS DP	U-868		
	>A> 5723606	Dec 15, 2019	DS DP	U-698		
<u>DAPTOMYCIN - CUBICIN</u>						
021572 002	RE39071	Jun 15, 2016	DS DP	U-728		
<u>DARIFENACIN HYDROBROMIDE - ENABLEX</u>						
021513 001	5096890	Mar 13, 2015	DS DP	U-631		
<u>DARIFENACIN HYDROBROMIDE - ENABLEX</u>						
021513 002	5096890	Mar 13, 2015	DS DP	U-631		
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
021976 002					NCE	Jun 23, 2011
<u>DESVENLAFAXINE SUCCINATE - PRISTIQ</u>						
021992 001	6673838	Feb 11, 2022	DS DP	U-860	NCE	Mar 01, 2013
	7291347	Feb 11, 2022	DP			
<u>DESVENLAFAXINE SUCCINATE - PRISTIQ</u>						
021992 002	6673838	Feb 11, 2022	DS DP	U-860	NCE	Mar 01, 2013
	7291347	Feb 11, 2022	DP			
<u>DEXMETHYLPHENIDATE HYDROCHLORIDE - FOCALIN XR</u>						
021802 001					>A> M-74	Apr 11, 2009
<u>DEXMETHYLPHENIDATE HYDROCHLORIDE - FOCALIN XR</u>						
021802 002					>A> M-74	Apr 11, 2009
<u>DEXMETHYLPHENIDATE HYDROCHLORIDE - FOCALIN XR</u>						
021802 003					>A> M-74	Apr 11, 2009
<u>DEXMETHYLPHENIDATE HYDROCHLORIDE - FOCALIN XR</u>						
021802 004					>A> M-74	Apr 11, 2009
<u>DEXTROAMPHETAMINE SULFATE - DEXTROAMPHETAMINE SULFATE</u>						
076814 001					PC	Aug 04, 2008
<u>DIVALPROEX SODIUM - DEPAKOTE</u>						
019680 001					M-34 PED	Mar 24, 2011 Sep 24, 2011
<u>DIVALPROEX SODIUM - DEPAKOTE ER</u>						
021168 001					M-34 PED	Mar 24, 2011 Sep 24, 2011

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<u>DIVALPROEX SODIUM - DEPAKOTE ER</u>						
021168 002					M-34 PED	Mar 24, 2011 Sep 24, 2011
<u>DONEPEZIL HYDROCHLORIDE - ARICEPT</u>						
020690 001	6372760	Mar 31, 2019		Y		
<u>DONEPEZIL HYDROCHLORIDE - ARICEPT</u>						
020690 002	6372760	Mar 31, 2019		Y		
<u>DORZOLAMIDE HYDROCHLORIDE; TIMOLOL MALEATE - COSOPT</u>						
020869 001	6248735	Apr 17, 2011		Y		
	6316443	Apr 17, 2011	DP U-561	Y		
<u>EFAVIRENZ; EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE - ATRIPLA</u>						
021937 001	>A> 5914331	Jul 02, 2017	DS			
	>A> 5914331*PED	Jan 02, 2018				
<u>ELETRIPTAN HYDROBROMIDE - RELPAX</u>						
021016 001	6110940	Aug 29, 2017				
<u>ELETRIPTAN HYDROBROMIDE - RELPAX</u>						
021016 002	6110940	Aug 29, 2017				
<u>EMTRICITABINE - EMTRIVA</u>						
021500 001	>A> 5914331	Jul 02, 2017	DS			
	>A> 5914331*PED	Jan 02, 2018				
<u>EMTRICITABINE - EMTRIVA</u>						
021896 001	>A> 5914331	Jul 02, 2017	DS			
	>A> 5914331*PED	Jan 02, 2018				
<u>EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE - TRUVADA</u>						
021752 001	>A> 5914331	Jul 02, 2017	DS DP U-248			
	>A> 5914331*PED	Jan 02, 2018	DS			
<u>ENFUVRTIDE - FUZEON</u>						
021481 001	>A> 6133418	Nov 17, 2014	DS DP			
<u>ENTECAVIR - BARACLUDE</u>						
021797 001	5206244	Feb 21, 2015	DS			
<u>ENTECAVIR - BARACLUDE</u>						
021797 002	5206244	Feb 21, 2015	DS			
<u>ENTECAVIR - BARACLUDE</u>						
021798 001	5206244	Feb 21, 2015	DS			
<u>EPLERENONE - INSPRA</u>						
021437 001					M-72 PED	Jan 31, 2011 Jul 31, 2011
<u>EPLERENONE - INSPRA</u>						
021437 002					M-72 PED	Jan 31, 2011 Jul 31, 2011
<u>ERTAPENEM SODIUM - INVANZ</u>						
021337 001	>A> 7342005	Feb 02, 2013	DP			
	>A> 7342005*PED	Aug 02, 2013				

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<u>ESCITALOPRAM OXALATE - LEXAPRO</u>						
021323 001	6916941	Aug 12, 2022	DS DP			
	6916941*PED	Feb 12, 2023	DS DP			
<u>ESCITALOPRAM OXALATE - LEXAPRO</u>						
021323 002	6916941	Aug 12, 2022	DS DP			
	6916941*PED	Feb 12, 2023	DS DP			
<u>ESCITALOPRAM OXALATE - LEXAPRO</u>						
021323 003	6916941	Aug 12, 2022	DS DP			
	6916941*PED	Feb 12, 2023	DS DP			
<u>ESOMEPRAZOLE MAGNESIUM - NEXIUM</u>						
022101 001	5690960	Nov 25, 2014	DP U-858		I-504	Oct 11, 2009
	5690960*PED	May 25, 2015			NPP	Feb 27, 2011
	5714504	Feb 03, 2015	DP U-858			
	5714504*PED	Aug 03, 2015				
	5877192	May 27, 2014	U-858			
	5877192*PED	Nov 27, 2014				
	5900424	May 04, 2016	DS U-858			
	5900424*PED	Nov 04, 2016				
	6369085	May 25, 2018	DS DP U-858			
	6369085*PED	Nov 25, 2018				
	6428810	Nov 03, 2019	DP U-858			
	6428810*PED	May 03, 2020				
	6875872	May 27, 2014	DS			
	6875872*PED	Nov 27, 2014				
<u>ESTRADIOL; NORGESTIMATE - PREFEST</u>						
021040 001	7320970	Mar 30, 2020	DP U-844			
<u>ETHINYL ESTRADIOL; LEVONORGESTREL - SEASONIQUE</u>						
021840 001	7320969	Jan 30, 2024	U-828			
<u>ETRAVIRINE - INTELENCE</u>						
022187 001					NCE	Jan 18, 2013
<u>EXENATIDE SYNTHETIC - BYETTA</u>						
021773 001	5424286	Dec 01, 2016	U-653			
<u>EZETIMIBE - ZETIA</u>						
021445 001	5846966	Sep 21, 2013	U-474		I-493	May 23, 2009
	5846966*PED	Mar 21, 2014			PED	Nov 23, 2009
	7030106	Jan 25, 2022	DP			
	7030106*PED	Jul 25, 2022				
	RE37721	Oct 25, 2016	DS DP U-473			
	RE37721*PED	Apr 25, 2017				
<u>EZETIMIBE; SIMVASTATIN - VYTORIN</u>						
021687 001	5846966	Sep 21, 2013	DP U-593		M-60	Oct 03, 2009
	5846966*PED	Mar 21, 2014			M-58	Mar 16, 2009
	7229982	Dec 11, 2023	DP U-592		PED	Apr 03, 2010
	7229982*PED	Jun 11, 2024			PED	Sep 16, 2009
	RE37721	Oct 25, 2016	DS DP U-473			
	RE37721*PED	Apr 25, 2017				

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<u>EZETIMIBE; SIMVASTATIN - VYTORIN</u>						
021687 002	5846966	Sep 21, 2013	DP U-593		M-60	Oct 03, 2009
	5846966*PED	Mar 21, 2014			M-58	Mar 16, 2009
	7229982	Dec 11, 2023	DP U-592		PED	Apr 03, 2010
	7229982*PED	Jun 11, 2024			PED	Sep 16, 2009
	RE37721	Oct 25, 2016	DS DP U-473			
	RE37721*PED	Apr 25, 2017				
<u>EZETIMIBE; SIMVASTATIN - VYTORIN</u>						
021687 003	5846966	Sep 21, 2013	DP U-593		M-60	Oct 03, 2009
	5846966*PED	Mar 21, 2014			M-58	Mar 16, 2009
	7229982	Dec 11, 2023	DP U-592		PED	Apr 03, 2010
	7229982*PED	Jun 11, 2024			PED	Sep 16, 2009
	RE37721	Oct 25, 2016	DS DP U-473			
	RE37721*PED	Apr 25, 2017				
<u>EZETIMIBE; SIMVASTATIN - VYTORIN</u>						
021687 004	5846966	Sep 21, 2013	DP U-593		M-60	Oct 03, 2009
	5846966*PED	Mar 21, 2014			M-58	Mar 16, 2009
	7229982	Dec 11, 2023	DP U-592		PED	Apr 03, 2010
	7229982*PED	Jun 11, 2024			PED	Sep 16, 2009
	RE37721	Oct 25, 2016	DS DP U-473			
	RE37721*PED	Apr 25, 2017				
<u>FAMOTIDINE - PEPCID AC</u>						
020801 001	>A> 5075114	Oct 23, 2010				
	>A> 5075114*PED	Nov 23, 2010				
	5667794	May 02, 2015			Y	
<u>FAMOTIDINE - PEPCID AC</u>						
020801 002	>A> 5075114	May 23, 2010	DP			
	>A> 5075114*PED	Nov 23, 2010				
	>A> 6814978	Aug 26, 2021	DP			
	>A> 6814978*PED	Feb 26, 2022				
<u>FENOFIBRATE - TRICOR</u>						
021656 001	7320802	Feb 21, 2023	U-847			
<u>FENOFIBRATE - TRICOR</u>						
021656 002	7320802	Feb 21, 2023	U-847			
<u>FENTANYL CITRATE - FENTORA</u>						
021947 006	6200604	Mar 26, 2019	U-767			
	6974590	Mar 26, 2019	U-767			
<u>FEXOFENADINE HYDROCHLORIDE - FEXOFENADINE HYDROCHLORIDE</u>						
077081 002					>A> PC	Oct 21, 2008
<u>FEXOFENADINE HYDROCHLORIDE - FEXOFENADINE HYDROCHLORIDE</u>						
077081 003					>A> PC	Oct 21, 2008
<u>FLUOCINONIDE - VANOS</u>						
021758 001	7220424	Jan 07, 2023	U-861			
<u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u>						
021520 002	5945416	Mar 24, 2017	DS DP		Y	

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<u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u>						
021520 003	5945416	Mar 24, 2017	DS DP	Y		
<u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u>						
021520 004	5945416	Mar 24, 2017	DS DP	Y		
<u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u>						
021520 005	5945416	Mar 24, 2017	DS DP	Y		
<u>FLUTICASONE PROPIONATE - FLOVENT HFA</u>						
021433 001	>A> 5658549	Aug 19, 2014	DP U-710			
<u>FLUTICASONE PROPIONATE - FLOVENT HFA</u>						
021433 002	>A> 5658549	Aug 19, 2014	DP U-710			
<u>FLUTICASONE PROPIONATE - FLOVENT HFA</u>						
021433 003	>A> 5658549	Aug 19, 2014	DP U-710			
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 100/50</u>						
021077 001	RE40045	Sep 07, 2010	DP		>A> I-558	Apr 30, 2011
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 250/50</u>						
021077 002	RE40045	Sep 07, 2010	DP		>A> I-558	Apr 30, 2011
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 500/50</u>						
021077 003	RE40045	Sep 07, 2010	DP		>A> I-558	Apr 30, 2011
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR HFA</u>						
021254 001	RE40045	Sep 07, 2010	DP			
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR HFA</u>						
021254 002	RE40045	Sep 07, 2010	DP			
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR HFA</u>						
021254 003	RE40045	Sep 07, 2010	DP			
<u>FLUVOXAMINE MALEATE - LUVOX CR</u>						
022033 001					NDF	Feb 28, 2011
<u>FLUVOXAMINE MALEATE - LUVOX CR</u>						
022033 002					NDF	Feb 28, 2011
<u>FORMOTEROL FUMARATE - PERFOROMIST</u>						
022007 001	>A> 7348362	Jun 22, 2021	DP			
<u>FOSAPREPITANT DIMEGLUMINE - EMEND</u>						
022023 001	5512570	Mar 04, 2014			U-850	
	5538982	Jul 23, 2013			U-850	
	5691336	Mar 04, 2014	DS DP			
	5716942	Feb 10, 2015			U-850	
	7214692	Sep 18, 2012			U-850	
<u>GADOBENATE DIMEGLUMINE - MULTIHANCE</u>						
021357 001	4916246	Apr 10, 2012	DS			
<u>GADOBENATE DIMEGLUMINE - MULTIHANCE</u>						
021357 002	4916246	Apr 10, 2012	DS			
<u>GADOBENATE DIMEGLUMINE - MULTIHANCE</u>						
021357 003	4916246	Apr 10, 2012	DS			



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<u>GADOBENATE DIMEGLUMINE - MULTIHANCE</u>						
021357 004	4916246	Apr 10, 2012	DS			
<u>GADOBENATE DIMEGLUMINE - MULTIHANCE MULTIPACK</u>						
021358 001	4916246	Apr 10, 2012	DS			
<u>GADOBENATE DIMEGLUMINE - MULTIHANCE MULTIPACK</u>						
021358 002	4916246	Apr 10, 2012	DS			
<u>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</u>						
021700 004	5002953	Sep 17, 2011	DS DP U-840			
<u>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</u>						
021700 005	5002953	Sep 17, 2011	DS DP U-840			
<u>GRANISETRON HYDROCHLORIDE - GRANISETRON HYDROCHLORIDE</u>						
077177 001					PC	Jun 28, 2008
<u>GRANISETRON HYDROCHLORIDE - GRANISETRON HYDROCHLORIDE PRESERVATIVE FREE</u>						
077165 001					PC	Jun 28, 2008
<u>HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM - HYZAAR</u>						
020387 001	5608075	Mar 04, 2014		Y		
<u>HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM - HYZAAR</u>						
020387 002	5608075	Mar 04, 2014		Y		
<u>INSULIN ASPART RECOMBINANT - NOVOLOG</u>						
020986 001					D-112	Mar 14, 2011
<u>LAMIVUDINE - EPIVIR</u>						
020564 001	5047407	Nov 17, 2009	DS DP U-257			
<u>LATANOPROST - XALATAN</u>						
020597 001	5422368	Mar 22, 2011	DP U-778	Y		
<u>LENALIDOMIDE - REVLIMID</u>						
021880 001	>A> 5635517	Oct 04, 2019	DS U-866			
<u>LENALIDOMIDE - REVLIMID</u>						
021880 002	>A> 5635517	Oct 04, 2019	DS U-866			
<u>LENALIDOMIDE - REVLIMID</u>						
021880 003	>A> 5635517	Oct 04, 2019	DS U-866			
<u>LENALIDOMIDE - REVLIMID</u>						
021880 004	>A> 5635517	Oct 04, 2019	DS U-866			
<u>LEVALBUTEROL HYDROCHLORIDE - XOPENEX</u>						
020837 001	>A> 5362755	Mar 25, 2013	U-332			
<u>LEVALBUTEROL HYDROCHLORIDE - XOPENEX</u>						
020837 002	>A> 5362755	Mar 25, 2013	U-332			
<u>LEVALBUTEROL HYDROCHLORIDE - XOPENEX</u>						
020837 003	>A> 5362755	Mar 25, 2013	U-332			
<u>LEVALBUTEROL HYDROCHLORIDE - XOPENEX</u>						
020837 004	>A> 5362755	Mar 25, 2013	U-332			
<u>LEVOCETIRIZINE DIHYDROCHLORIDE - XYZAL</u>						
022157 001	5698558	Sep 24, 2012	U-852		NP	May 25, 2010

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<u>LEVOLEUCOVORIN CALCIUM - LEVOLEUCOVORIN</u>						
020140 001	6500829	Dec 31, 2019	DS DP		NP ODE	Mar 07, 2011 Mar 07, 2015
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
021977 001					>A> NPP	Apr 23, 2011
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
021977 002					>A> NPP	Apr 23, 2011
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
021977 003					>A> NPP	Apr 23, 2011
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
021977 004	7105486	Jun 29, 2023		U-842	>A> NPP	Apr 23, 2011
	7223735	Jun 29, 2023	DP			
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
021977 005	7105486	Jun 29, 2023		U-842	>A> NPP	Apr 23, 2011
	7223735	Jun 29, 2023	DP			
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
021977 006	7105486	Jun 29, 2023		U-842	>A> NPP	Apr 23, 2011
	7223735	Jun 29, 2023	DP			
<u>LOPERAMIDE HYDROCHLORIDE; SIMETHICONE - IMODIUM MULTI-SYMPOM RELIEF</u>						
020606 001	5248505	Jul 28, 2010			Y	
	5612054	Sep 28, 2010			Y	
	5679376	Oct 21, 2014			Y	
	5716641	May 21, 2012		U-226	Y	
<u>LOPINAVIR; RITONAVIR - KALETRA</u>						
021226 001	5914332	Dec 13, 2015		U-351		
	5914332*PED	Jun 13, 2016				
	>A> 6284767	Feb 15, 2016		U-401		
	>A> 6284767*PED	Aug 15, 2016				
<u>LOPINAVIR; RITONAVIR - KALETRA</u>						
021251 001	5914332	Dec 13, 2015		U-351		
	5914332*PED	Jun 13, 2016				
	>A> 6284767	Feb 15, 2016		U-401		
	>A> 6284767*PED	Aug 15, 2016				
<u>LOPINAVIR; RITONAVIR - KALETRA</u>						
021906 001	5914332	Dec 13, 2015	DS DP	U-688		
	5914332*PED	Jun 13, 2016				
	>A> 6284767	Feb 15, 2016		DP	U-688	
	>A> 6284767*PED	Aug 15, 2016				
	7148359	Jul 19, 2019	DP			
	7148359*PED	Jan 19, 2020				

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<u>LOPINAVIR; RITONAVIR - KALETRA</u>						
021906 002	5541206	Jul 30, 2013	DS DP U-688			
	5541206*PED	Jan 30, 2014				
	5635523	Jun 03, 2014	U-688			
	5635523*PED	Dec 03, 2014				
	5648497	Jul 15, 2014	DS DP			
	5648497*PED	Jan 15, 2015				
	5674882	Oct 07, 2014	U-688			
	5674882*PED	Apr 07, 2015				
	5846987	Dec 29, 2012	U-688			
	5846987*PED	Jun 29, 2013				
	5886036	Nov 19, 2013	DS DP			
	5886036*PED	May 19, 2014				
	5914332	Dec 13, 2015	DS DP U-688			
	5914332*PED	Jun 13, 2016				
	6037157	Jun 26, 2016	U-688			
	6037157*PED	Dec 26, 2016				
	>A> 6284767	Feb 15, 2016	DP U-688			
	>A> 6284767*PED	Aug 15, 2016				
	6703403	Jun 26, 2016	U-688			
	6703403*PED	Dec 26, 2016				
	7148359	Jul 19, 2019	DP			
	7148359*PED	Jan 19, 2020				
<u>LOSARTAN POTASSIUM - COZAAR</u>						
020386 001	5608075	Mar 04, 2014		Y		
<u>LOSARTAN POTASSIUM - COZAAR</u>						
020386 002	5608075	Mar 04, 2014		Y		
<u>LOSARTAN POTASSIUM - COZAAR</u>						
020386 003	5608075	Mar 04, 2014		Y		
<u>LUBIPROSTONE - AMITIZA</u>						
021908 002					>A> I-557	Apr 28, 2011
					>A> NS	Apr 28, 2011
					>A> NCE	Jan 31, 2011
<u>MENTHOL; METHYL SALICYLATE - SALONPAS</u>						
022029 001					NDF	Feb 20, 2011
					NC	Feb 20, 2011
<u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u>						
021410 001	5741803	Apr 21, 2015	DS DP U-734	Y		
	5741803	Apr 21, 2015	DS DP U-493	Y		
	5965584	Jun 19, 2016	U-493	Y		
	6166042	Jun 19, 2016	U-493	Y		
	6288095	Feb 11, 2017	U-493	Y		
<u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u>						
021410 002	5741803	Apr 21, 2015	DS DP U-734	Y		
	5741803	Apr 21, 2015	DS DP U-493	Y		
	5965584	Jun 19, 2016	U-493	Y		
	6166042	Jun 19, 2016	U-493	Y		
	6288095	Feb 11, 2017	U-493	Y		

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<u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u>						
021410 003	5741803	Apr 21, 2015	DS DP U-734	Y		
	5741803	Apr 21, 2015	DS DP U-493	Y		
	5965584	Jun 19, 2016	U-493	Y		
	6166042	Jun 19, 2016	U-493	Y		
	6288095	Feb 11, 2017	U-493	Y		
<u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u>						
021410 004	5741803	Apr 21, 2015	DS DP U-734	Y		
	5741803	Apr 21, 2015	DS DP U-493	Y		
<u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u>						
021410 005	5741803	Apr 21, 2015	DS DP U-734	Y		
	5741803	Apr 21, 2015	DS DP U-493	Y		
<u>METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE - JANUMET</u>						
022044 001	7326708	Apr 11, 2026	DS DP U-802		>A> M-69 >A> M-68	Oct 12, 2010 Oct 12, 2010
<u>METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE - JANUMET</u>						
022044 002	7326708	Apr 11, 2026	DS DP U-802		>A> M-69 >A> M-68	Oct 12, 2010 Oct 12, 2010
<u>METHYLNALTREXONE BROMIDE - RELISTOR</u>						
021964 001					>A> NCE	Apr 24, 2013
<u>MICAFUNGIN SODIUM - MYCAMINE</u>						
021506 002	>A> 6107458	Mar 16, 2019	DS DP U-845		I-554	Jan 22, 2011
	>A> 6107458	Mar 16, 2019	DS DP U-650			
	6265536	Sep 29, 2015	DS DP U-845			
	6265536	Sep 29, 2015	DS DP U-650			
	6774104	Jan 08, 2021	DP U-845			
	6774104	Jan 08, 2021	DP U-650			
<u>MICAFUNGIN SODIUM - MYCAMINE</u>						
021506 003	5376634	Dec 27, 2011	DS DP		I-554 NCE	Jan 22, 2011 Mar 16, 2010
	>A> 6107458	Mar 16, 2019	DS DP U-845			
	>A> 6107458	Mar 16, 2019	DS DP U-650			
	6265536	Sep 29, 2015	DS DP U-845			
	6265536	Sep 29, 2015	DS DP U-650			
	6774104	Jan 08, 2021	DP U-845			
	6774104	Jan 08, 2021	DP U-650			
<u>MICONAZOLE NITRATE; PETROLATUM, WHITE; ZINC OXIDE - VUSION</u>						
021026 001	4911932	Mar 27, 2009	DP U-718			
<u>MODAFINIL - PROVIGIL</u>						
020717 001	7297346	Nov 29, 2023	DP			
<u>MODAFINIL - PROVIGIL</u>						
020717 002	7297346	Nov 29, 2023	DP			
<u>MOMETASONE FUROATE - ASMANEX TWISTHALER</u>						
021067 001					NPP	Feb 01, 2011

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<u>NAPROXEN SODIUM; SUMATRIPTAN SUCCINATE - TREXIMET</u>						
021926 001	>A> 5037845	Aug 06, 2008	DS DP U-867			
	>A> 6060499	Aug 14, 2017	DP U-867			
	>A> 6586458	Aug 14, 2017	DP U-867			
	>A> 7332183	Oct 02, 2025	DP U-867			
<u>NEBIVOLOL HYDROCHLORIDE - BYSTOLIC</u>						
021742 002	5759580	Jun 02, 2015	DP			
	6545040	Apr 08, 2020	DP U-3			
<u>NEBIVOLOL HYDROCHLORIDE - BYSTOLIC</u>						
021742 003	5759580	Jun 02, 2015	DP			
	6545040	Apr 08, 2020	DP U-3			
<u>NEBIVOLOL HYDROCHLORIDE - BYSTOLIC</u>						
021742 004	5759580	Jun 02, 2015	DP			
	6545040	Apr 08, 2020	DP U-3			
<u>NESIRITIDE RECOMBINANT - NATRECOR</u>						
020920 001	5114923	May 19, 2014	DS DP U-855			
<u>NIACIN; SIMVASTATIN - SIMCOR</u>						
022078 001	6080428	May 27, 2017	U-862		NC	Feb 15, 2011
	6129930	Sep 20, 2013	DP U-862			
	6406715	Sep 20, 2013	DP			
	6469035	Mar 15, 2018	U-863			
	6676967	Sep 20, 2013	U-862			
	6746691	Sep 20, 2013	DP			
	6818229	Feb 15, 2014	DP			
	7011848	Sep 20, 2013	U-862			
<u>NIACIN; SIMVASTATIN - SIMCOR</u>						
022078 002	6080428	May 27, 2017	U-862		NC	Feb 15, 2011
	6129930	Sep 20, 2013	DP U-862			
	6406715	Sep 20, 2013	DP			
	6469035	Mar 15, 2018	U-863			
	6676967	Sep 20, 2013	U-862			
	6746691	Sep 20, 2013	DP			
	6818229	Feb 15, 2014	DP			
	7011848	Sep 20, 2013	U-862			
<u>NIACIN; SIMVASTATIN - SIMCOR</u>						
022078 003	6080428	May 27, 2017	U-862		NC	Feb 15, 2011
	6129930	Sep 20, 2013	DP U-862			
	6406715	Sep 20, 2013	DP			
	6469035	Mar 15, 2018	U-863			
	6676967	Sep 20, 2013	U-862			
	6746691	Sep 20, 2013	DP			
	6818229	Feb 15, 2014	DP			
	7011848	Sep 20, 2013	U-862			
<u>NILOTINIB HYDROCHLORIDE MONOHYDRATE - TASIGNA</u>						
022068 001					ODE	Oct 29, 2014

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<u>NISOLDIPINE - SULAR</u>						
020356 005	5422123	Jun 06, 2012	DP			
	5626874	Nov 30, 2014	DP			
<u>NISOLDIPINE - SULAR</u>						
020356 006	5422123	Jun 06, 2012	DP			
	5626874	Nov 30, 2014	DP			
<u>NISOLDIPINE - SULAR</u>						
020356 007	5422123	Jun 06, 2012	DP			
	5626874	Nov 30, 2014	DP			
<u>NISOLDIPINE - SULAR</u>						
020356 008	5422123	Jun 06, 2012	DP			
	5626874	Nov 30, 2014	DP			
<u>OCTREOTIDE ACETATE - SANDOSTATIN LAR</u>						
021008 001					>A> M-73	Mar 03, 2011
<u>OCTREOTIDE ACETATE - SANDOSTATIN LAR</u>						
021008 002					>A> M-73	Mar 03, 2011
<u>OCTREOTIDE ACETATE - SANDOSTATIN LAR</u>						
021008 003					>A> M-73	Mar 03, 2011
<u>OLMESARTAN MEDOXOMIL - BENICAR</u>						
021286 001	6878703	Nov 19, 2021	U-3	Y		
<u>OLMESARTAN MEDOXOMIL - BENICAR</u>						
021286 003	6878703	Nov 19, 2021	U-3	Y		
<u>OLMESARTAN MEDOXOMIL - BENICAR</u>						
021286 004	6878703	Nov 19, 2021	U-3	Y		
<u>OLOPATADINE HYDROCHLORIDE - PATANASE</u>						
021861 001	>A> 5116863	Dec 18, 2010	DS DP			
<u>OMEPRAZOLE MAGNESIUM - PRILOSEC</u>						
022056 001	>A> 5690960	Nov 25, 2014	DP U-864		NPP	Mar 20, 2011
	>A> 5900424	May 04, 2016	DS U-864		PED	Sep 20, 2011
	>A> 6428810	Nov 03, 2019	DP U-864			
<u>OMEPRAZOLE MAGNESIUM - PRILOSEC</u>						
022056 002	>A> 5690960	Nov 25, 2014	DP U-864		NPP	Mar 20, 2011
	>A> 5900424	May 04, 2016	DS U-864		PED	Sep 20, 2011
	>A> 6428810	Nov 03, 2019	DP U-864			
<u>OXCARBAZEPINE - OXCARBAZEPINE</u>						
078069 001					PC	Apr 06, 2008
<u>OXCARBAZEPINE - OXCARBAZEPINE</u>						
078069 002					PC	Apr 06, 2008
<u>OXCARBAZEPINE - OXCARBAZEPINE</u>						
078069 003					PC	Apr 06, 2008

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<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
021610 005	>A> 5128143	Sep 19, 2008	DP		NDF	Jun 22, 2009
	>A> 5662933	Sep 09, 2013	DP			
	>A> 5958456	Sep 09, 2013	DP			
	>A> 7276250	Jul 03, 2022	DP U-826			
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
021610 006	>A> 5128143	Sep 19, 2008	DP		NDF	Jun 22, 2009
	>A> 5662933	Sep 09, 2013	DP			
	>A> 5958456	Sep 09, 2013	DP			
	>A> 7276250	Jul 03, 2022	DP U-826			
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
021610 007	>A> 5128143	Sep 19, 2008	DP		NDF	Jun 22, 2009
	>A> 5662933	Sep 09, 2013	DP			
	>A> 5958456	Sep 09, 2013	DP			
	>A> 7276250	Jul 03, 2022	DP U-826			
<u>PALONOSETRON HYDROCHLORIDE - ALOXI</u>						
021372 002					I-556 NS NCE	Mar 01, 2011 Mar 01, 2011 Jul 25, 2008
<u>PANTOPRAZOLE SODIUM - PANTOPRAZOLE SODIUM</u>						
077056 001					PC	Jun 18, 2008
<u>PANTOPRAZOLE SODIUM - PANTOPRAZOLE SODIUM</u>						
077056 002					PC	Jun 18, 2008
<u>PANTOPRAZOLE SODIUM - PANTOPRAZOLE SODIUM</u>						
077058 001					PC	Jun 18, 2008
<u>PANTOPRAZOLE SODIUM - PANTOPRAZOLE SODIUM</u>						
077058 002					PC	Jun 18, 2008
<u>PANTOPRAZOLE SODIUM - PROTONIX</u>						
022020 001	4758579	Jul 19, 2010	DS DP U-859			
<u>PANTOPRAZOLE SODIUM - PROTONIX IV</u>						
020988 001	>A> 7351723	Nov 17, 2021	DP			
<u>PEMETREXED DISODIUM - ALIMTA</u>						
021462 002	5217974	Mar 29, 2011	U-551			
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>						
020667 001	4886812	Oct 08, 2010	DS DP			
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>						
020667 002	4886812	Oct 08, 2010	DS DP			
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>						
020667 003	4886812	Oct 08, 2010	DS DP			
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>						
020667 004	4886812	Oct 08, 2010	DS DP			
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>						
020667 005	4886812	Oct 08, 2010	DS DP			
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>						
020667 006	4886812	Oct 08, 2010	DS DP			

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<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>						
020667 007	4886812	Oct 08, 2010	DS DP		I-517	Nov 07, 2009
	6001861	Jan 16, 2018		U-784		
	6194445	Jan 16, 2018		U-784		
<u>PREDNISOLONE ACETATE - FLO-PRED</u>						
022067 001	5881926	Mar 16, 2016	DP			
	6071523	Jun 03, 2018	DP			
	6102254	Mar 11, 2013	DP			
	6399079	Jun 03, 2018	DP			
	6656482	Jun 03, 2018	DP			
<u>PREDNISOLONE ACETATE - FLO-PRED</u>						
022067 002	5881926	Mar 16, 2016	DP			
	6071523	Jun 03, 2018	DP			
	6102254	Mar 11, 2013	DP			
	6399079	Jun 03, 2018	DP			
	6656482	Jun 03, 2018	DP			
<u>PREDNISOLONE SODIUM PHOSPHATE - ORAPRED ODT</u>						
021959 001	>A> 6024981	Apr 09, 2018	DP			
	>A> 6221392	Apr 09, 2018	DP			
<u>PREDNISOLONE SODIUM PHOSPHATE - ORAPRED ODT</u>						
021959 002	>A> 6024981	Apr 09, 2018	DP			
	>A> 6221392	Apr 09, 2018	DP			
<u>PREDNISOLONE SODIUM PHOSPHATE - ORAPRED ODT</u>						
021959 003	>A> 6024981	Apr 09, 2018	DP			
	>A> 6221392	Apr 09, 2018	DP			
<u>PROGESTERONE - ENDOMETRIN</u>						
022057 001	7300664	Nov 17, 2019	U-856			
	7320800	Nov 17, 2019	U-856			
<u>RALOXIFENE HYDROCHLORIDE - EVISTA</u>						
020815 001	5393763	Jul 28, 2012	U-114	Y	ODE	Sep 13, 2014
	5457117	Jul 28, 2012	U-114	Y		
	5478847	Mar 02, 2014	U-114	Y		
<u>REGADENOSON - LEXISCAN</u>						
022161 001	>A> 6403567	Jun 22, 2019	DS DP U-869		>A> NCE	Apr 10, 2013
	>A> 6642210	Jun 22, 2019	DS DP U-869			
	>A> 7144872	Jun 22, 2019	DS DP U-870			
	>A> 7144872	Jun 22, 2019	DS DP U-869			
	>A> 7144872	Jun 22, 2019	DS DP U-116			
	>A> 7183264	Jun 22, 2019	DP U-870			
	>A> 7183264	Jun 22, 2019	DP U-869			
	>A> 7183264	Jun 22, 2019	DP U-116			
<u>RISPERIDONE - RISPERDAL</u>						
020588 001	5616587	Jul 11, 2014		Y		
<u>ROCURONIUM BROMIDE - ZEMURON</u>						
020214 001	4894369	Apr 13, 2008				
	4894369*PED	Oct 13, 2008				



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<u>ROCURONIUM BROMIDE - ZEMURON</u>						
020214 002	4894369	Apr 13, 2008				
	4894369*PED	Oct 13, 2008				
<u>ROCURONIUM BROMIDE - ZEMURON</u>						
020214 003	4894369	Apr 13, 2008				
	4894369*PED	Oct 13, 2008				
<u>ROSIGLITAZONE MALEATE - AVANDIA</u>						
021071 002	5741803	Apr 21, 2015	DS DP U-628	Y		
	5741803	Apr 21, 2015	DS DP U-329	Y		
	6288095	Feb 11, 2017	U-420	Y		
<u>ROSIGLITAZONE MALEATE - AVANDIA</u>						
021071 003	5741803	Apr 21, 2015	DS DP U-628	Y		
	5741803	Apr 21, 2015	DS DP U-329	Y		
	6288095	Feb 11, 2017	U-420	Y		
<u>ROSIGLITAZONE MALEATE - AVANDIA</u>						
021071 004	5741803	Apr 21, 2015	DS DP U-628	Y		
	5741803	Apr 21, 2015	DS DP U-329	Y		
	6288095	Feb 11, 2017	U-420	Y		
<u>SEVELAMER CARBONATE - RENVELA</u>						
022127 001	5496545	Aug 11, 2013	DP U-246			
	5667775	Sep 16, 2014	U-246			
	6509013	Aug 11, 2013	DP			
	6858203	Aug 11, 2013	DP U-246			
	7014846	Aug 11, 2013	DP U-246			
<u>SIROLIMUS - RAPAMUNE</u>						
021083 001					>A> D-114	Jan 30, 2010
<u>SIROLIMUS - RAPAMUNE</u>						
021110 001	5145684	Jan 25, 2011	DP U-857		>A> D-114	Jan 30, 2010
	5145684*PED	Jul 25, 2011				
<u>SIROLIMUS - RAPAMUNE</u>						
021110 002	5145684	Jan 25, 2011	DP U-857		>A> D-114	Jan 30, 2010
	5145684*PED	Jul 25, 2011				
<u>SIROLIMUS - RAPAMUNE</u>						
021110 003	5145684	Jan 25, 2011	DP U-857			
	5145684*PED	Jul 25, 2011				
<u>SITAGLIPTIN PHOSPHATE - JANUVIA</u>						
021995 001	7326708	Apr 11, 2026	DS DP U-802			
<u>SITAGLIPTIN PHOSPHATE - JANUVIA</u>						
021995 002	7326708	Apr 11, 2026	DS DP U-802			
<u>SITAGLIPTIN PHOSPHATE - JANUVIA</u>						
021995 003	7326708	Apr 11, 2026	DS DP U-802			
<u>SODIUM OXYBATE - XYREM</u>						
021196 001	6780889	Jul 04, 2020	DP			
	7262219	Jul 04, 2020	DP			

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<u>SOMATROPIN RECOMBINANT - ACCRETROPIN</u>						
021538 001					NP	Jan 23, 2011
<u>SOMATROPIN RECOMBINANT - OMNITROPE</u>						
021426 003					NP	May 30, 2009
<u>SORAFENIB TOSYLATE - NEXAVAR</u>						
021923 001	>A> 7351834	Jan 12, 2020	DS		ODE	Nov 16, 2014
<u>SUMATRIPTAN SUCCINATE - IMITREX</u>						
020132 001	5863559	Jan 26, 2016	U-72	Y		
	6020001	Mar 02, 2012	U-444	Y		
	6368627	Mar 02, 2012	U-444	Y		
<u>SUMATRIPTAN SUCCINATE - IMITREX</u>						
020132 002	5863559	Jan 26, 2016	U-72	Y		
	6020001	Mar 02, 2012	U-444	Y		
	6368627	Mar 02, 2012	U-444	Y		
<u>SUMATRIPTAN SUCCINATE - IMITREX</u>						
020132 003	5863559	Jan 26, 2016	U-72	Y		
	6020001	Mar 02, 2012	U-444	Y		
	6368627	Mar 02, 2012	U-444	Y		
<u>SUMATRIPTAN SUCCINATE - IMITREX STATDOSE</u>						
020080 002	5037845	Aug 06, 2008	DS DP U-848			
	5037845*PED	Feb 06, 2009				
<u>TADALAFIL - CIALIS</u>						
021368 001					D-111	Jan 07, 2011
<u>TADALAFIL - CIALIS</u>						
021368 004	5859006	Nov 21, 2017	DS DP		D-111	Jan 07, 2011
	6140329	Jul 11, 2016	DP U-155		NCE	Nov 21, 2008
	6821975	Nov 19, 2020	DS DP U-614			
	6821975	Nov 19, 2020	DS DP U-533			
	6943166	Apr 26, 2020	U-155			
	7182958	Apr 26, 2020	DP U-155			
<u>TECHNETIUM TC-99M SESTAMIBI KIT - CARDIOLITE</u>						
019785 001	4988827	Jan 29, 2008				
	4988827*PED	Jul 29, 2008				
<u>TERBINAFINE - LAMISIL AT</u>						
021958 001	6121314	May 18, 2012	U-540			
	6121314	May 18, 2012	U-504			
<u>TERIPARATIDE RECOMBINANT HUMAN - FORTEO</u>						
021318 001	>A> 7351414	Aug 19, 2019	U-865			
<u>TESTOSTERONE - TESTIM</u>						
021454 001	7320968	Jan 18, 2025	U-843			
<u>TIGECYCLINE - TYGACIL</u>						
021821 001	RE40086	Jun 25, 2013	U-282			
	>A> RE40183	Apr 09, 2016	DS DP			

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<u>TIOTROPIUM BROMIDE MONOHYDRATE - SPIRIVA</u>						
021395 001	5478578	Dec 26, 2012	DP			
	7309707	Mar 10, 2023	DS DP			
<u>TIPRANA VIR - APTIVUS</u>						
021814 001	5852195	Jun 22, 2019	DS		NCE	Jun 22, 2010
	5852195*PED	Dec 22, 2019			PED	Dec 22, 2010
	6147095	Oct 29, 2019		U-670		
	6147095*PED	Apr 29, 2020				
	6169181	May 06, 2014	DS			
	6169181*PED	Nov 06, 2014				
	6231887	Jul 27, 2018	DP			
	6231887*PED	Jan 27, 2019				
<u>TRIAMCINOLONE ACETONIDE - TRIESENCE</u>						
022048 001	6395294	Jan 13, 2020	DP U-846			
<u>VALACYCLOVIR HYDROCHLORIDE - VALTREX</u>						
020487 001	4957924	Jun 23, 2009	U-530			
	4957924*PED	Dec 23, 2009				
	5879706	Jan 19, 2016	U-530			
	5879706*PED	Jul 19, 2016				
	6107302	Jan 19, 2016	U-530			
	6107302*PED	Jul 19, 2016				
<u>VALACYCLOVIR HYDROCHLORIDE - VALTREX</u>						
020487 002	4957924	Jun 23, 2009	U-530			
	4957924*PED	Dec 23, 2009				
	5879706	Jan 19, 2016	U-530			
	5879706*PED	Jul 19, 2016				
	6107302	Jan 19, 2016	U-530			
	6107302*PED	Jul 19, 2016				
<u>VALGANCICLOVIR HYDROCHLORIDE - VALCYTE</u>						
021304 001	6083953	Mar 29, 2015	DS DP U-854			
	6083953	Mar 29, 2015	DS DP U-384			
<u>ZOLEDRONIC ACID - ZOMETA</u>						
021223 002					>A> ODE	Aug 20, 2008
					>A> PED	Feb 20, 2009

## 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 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.

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2008

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

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>070012 001</u>				NP	Dec 10, 2010

## 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, 28<sup>th</sup> 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>