

# **APPROVED DRUG PRODUCTS**

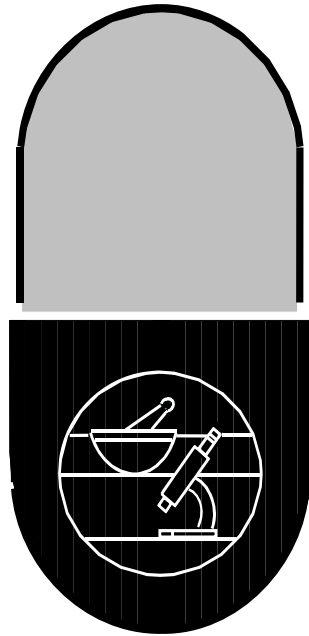
## **With Therapeutic Equivalence Evaluations**



**The "Orange Book"**

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**CUMULATIVE  
SUPPLEMENT 05  
May 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**

2008

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

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

**Cumulative Supplement 05**

**May 2008**

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

**CUMULATIVE SUPPLEMENT 05  
May 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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 SQUIBB)	LANTHEUS MEDICAL IMAGING INC (LANTHEUS MEDCL)
CIS US INC (CIS)	PHARMALUCENCE INC (PHARMALUCENCE)
CONNETICS CORP (CONNETICS)	STIEFEL LABORATORIES INC (STIEFEL LABS INC)
GLENMARK PHARMACEUTICALS INC USA (GLENMARK PHARMA)	GLENMARK GENERICS INC USA (GLENMARK GENERICS)
GLENMARK PHARMACEUTICALS INC USA (GLENMARK PHARMS INC)	GLENMARK GENERICS LTD (GLENMARK GENERICS)
GLENMARK PHARMACEUTICALS INC USA (GLENMARK PHARMA)	GLENMARK GENERICS LTD (GLENMARK GENERICS)
GLENMARK PHARMACEUTICALS LTD	GLENMARK GENERICS INC USA

(GLENMARK PHARMS)  
GLENMARK PHARMACEUTICALS LTD  
(GLENMARK PHARMS)

(GLENMARK GENERICS)  
GLENMARK GENERICS LTD  
(GLENMARK GENERICS)

GLENMARK PHARMACEUTICALS LTD INDIA  
(GLENMARK PHARMS LTD)

GLENMARK GENERICS LTD  
(GLENMARK GENERICS)

RELIANT PHARMACEUTICALS LLC  
(RELIANT PHARMS)

SMITHKLINE BEECHAM 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://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 5 - May 2008

1-1

ACARBOSE

TABLET; ORAL

ACARBOSE

AB	COBALT LABS INC	25MG	N77532 001	May 07, 2008	Apr	NEWA
AB		50MG	N77532 002	May 07, 2008	Apr	NEWA
AB		100MG	N77532 003	May 07, 2008	Apr	NEWA
AB	ROXANE	25MG	N78470 001	May 07, 2008	Apr	NEWA
AB		50MG	N78470 002	May 07, 2008	Apr	NEWA
AB		100MG	N78470 003	May 07, 2008	Apr	NEWA
PRECLOSE						
AB	BAYER PHARMS	25MG	N20482 004	May 29, 1997	Apr	CFTG
AB		50MG	N20482 001	Sep 06, 1995	Apr	CFTG
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; CAFFEINE; DIHYDROCODEINE BITARTRATE

CAPSULE; ORAL

DHC PLUS

>A>	@ PHARM RES ASSOC	356.4MG;30MG;16MG	N88584 001	Mar 04, 1986	May	CAHN
>D>	@ PURDUE FREDERICK	356.4MG;30MG;16MG	N88584 001	Mar 04, 1986	May	CAHN

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

>A>	AA	INTERPHARM	300MG;30MG	N40779 001	May 29, 2008	May	NEWA
		@ 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
+	PHARM ASSOC	325MG/15ML;10MG/15ML	N40834 001	Apr 18, 2008	Apr	NEWA

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
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ACETOHEXAMIDE

TABLET; ORAL

ACETOHEXAMIDE

	@ BARR	250MG	N70869 001	Feb 09, 1987	Feb	DISC
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## TABLET; ORAL

ACETOHEXAMIDE									
@ BARR	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									
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

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

## TABLET; ORAL

LOTRONEX

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

## TABLET, EXTENDED RELEASE; ORAL

ALPRAZOLAM

>A>	AB	INTERPHARM	0.5MG	N78387 001	May 30, 2008	May	NEWA
>A>	AB		1MG	N78387 002	May 30, 2008	May	NEWA
>A>	AB		2MG	N78387 003	May 30, 2008	May	NEWA
>A>	AB		3MG	N78387 004	May 30, 2008	May	NEWA

>A> ALVIMOPAN

## &gt;A&gt; CAPSULE; ORAL

&gt;A&gt; ENTEREG

>A>	+	ADOLOR	12MG	N21775 001	May 20, 2008	May	NEWA
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AMANTADINE HYDROCHLORIDE

## CAPSULE; ORAL

AMANTADINE HYDROCHLORIDE

>A>	AB	BANNER PHARMACAPS	100MG	N78720 001	May 29, 2008	May	NEWA
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## 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
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ETHYOL

>A>		@ MEDIMMUNE	375MG/VIAL	N20221 002	Sep 10, 1999	May	CAHN
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>A>	AP	+	500MG/VIAL	N20221 001	Dec 08, 1995	May	CAHN
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>D>		@ MEDIMMUNE ONCOLOGY	375MG/VIAL	N20221 002	Sep 10, 1999	May	CAHN
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>D>	AP	+	500MG/VIAL	N20221 001	Dec 08, 1995	May	CAHN
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AP	+	500MG/VIAL	N20221 001	Dec 08, 1995	Mar	CFTG
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AMINOPHYLLINE

## TABLET, EXTENDED RELEASE; ORAL

PHYLLOCONTIN

>A>		@ PHARM RES ASSOC	225MG	N86760 001		May	CAHN
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>D>		@ PURDUE FREDERICK	225MG	N86760 001		May	CAHN
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AMIODARONE HYDROCHLORIDE

## INJECTABLE; INJECTION

AMIODARONE HYDROCHLORIDE

		@ BEN VENUE	50MG/ML	N76088 001	Oct 15, 2002	Apr	DISC
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AP		HIKMA FARMACEUTICA	50MG/ML	N77234 001	Feb 25, 2008	Feb	NEWA
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## TABLET; ORAL

AMIODARONE HYDROCHLORIDE

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

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

ASPIRIN; CARISOPRODOL

TABLET; ORAL

SOMA COMPOUND

>A>	AB	+	MEDA PHARMS	325MG;200MG	N12365 005	Jul 11, 1983	May	CAHN
>D>	AB	+	MEDPOINTE PHARM HLC	325MG;200MG	N12365 005	Jul 11, 1983	May	CAHN

ASPIRIN; CARISOPRODOL; CODEINE PHOSPHATE

TABLET; ORAL

SOMA COMPOUND W/ CODEINE

>A>	AB	+	MEDA PHARMS	325MG;200MG;16MG	N12366 002	Jul 11, 1983	May	CAHN
>D>	AB	+	MEDPOINTE PHARM HLC	325MG;200MG;16MG	N12366 002	Jul 11, 1983	May	CAHN

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

@ PVT FORM	0.025MG;2.5MG	N85766 001		Apr	CAHN
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ATROPINE SULFATE; EDROPHONIUM CHLORIDE

INJECTABLE; INJECTION

ENLON-PLUS

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

TABLET; ORAL

AZITHROMYCIN

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

INJECTABLE; INJECTION

AZACTAM

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

TABLET; ORAL

BENAZEPRIL HYDROCHLORIDE

>A>	AB	AUROBINDO PHARMA	10MG	N78212 001	May 22, 2008	May	NEWA
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>A>	AB		20MG	N78212 002	May 22, 2008	May	NEWA
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>A>	AB		40MG	N78212 003	May 22, 2008	May	NEWA
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>A>	AB	ZYDUS PHARMS USA	5MG	N78848 001	May 23, 2008	May	NEWA
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>A>	AB		10MG	N78848 002	May 23, 2008	May	NEWA
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>A>	AB		20MG	N78848 003	May 23, 2008	May	NEWA
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>A>	AB		40MG	N78848 004	May 23, 2008	May	NEWA
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BENDAMUSTINE HYDROCHLORIDE

POWDER; IV (INFUSION)

TREANDA

+	CEPHALON	100MG/VIAL	N22249 001	Mar 20, 2008	Mar	NEWA
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BENDROFLUMETHIAZIDE; NADOLOL

TABLET; ORAL

NADOLOL AND BENDROFLUMETHAZIDE

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

CAPSULE; ORAL

BENZONATATE

>A>	AA	BANNER PHARMACAPS	200MG	N81297 002	Oct 30, 2007	May	NEWA
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AA	ORIT LABS LLC	100MG	N40682 001	Jul 30, 2007	Jan	CAHN
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AA		200MG	N40682 002	Jul 30, 2007	Jan	CAHN
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AA	SUN PHARM INDS INC	100MG	N40587 001	Mar 19, 2008	Mar	NEWA
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AA		200MG	N40587 002	Mar 19, 2008	Mar	NEWA
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BENZTHIAZIDE

TABLET; ORAL

BENZTHIAZIDE

@ PVT FORM	50MG	N83206 001		Apr	CAHN
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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

BETAMETHASONE DIPROPIONATE; CALCIPOTRIENE HYDRATE

&gt;A&gt; SUSPENSION; TOPICAL

&gt;A&gt; TACLONEX SCALP

>A>	+ LEO PHARM PRODS	0.064%;0.005%	N22185 001	May 09, 2008	May	NEWA
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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

BISACODYL; POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE

FOR SOLUTION; ORAL

HALFLYTELY

>D>	+ BRAINTREE	5MG,N/A;N/A,21.0GM;N/A,0.74GM;N/A,2.86GM;N/A,5.6GM	N21551 001	May 10, 2004	May	DISC
>A>	@	5MG,N/A;N/A,21.0GM;N/A,0.74GM;N/A,2.86GM;N/A,5.6GM	N21551 001	May 10, 2004	May	DISC

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

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

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

&gt;D&gt; INJECTABLE; INJECTION

&gt;D&gt; DUOCAINE

>D>	+	AMPHASTAR	EQ 0.375% (37.5MG/10ML);EQ 1% (100MG/10ML)	N21496	001	May 23, 2003	May	DISC
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>A>	@		EQ 0.375% (37.5MG/10ML);EQ 1% (100MG/10ML)	N21496	001	May 23, 2003	May	DISC
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BUPROPION HYDROBROMIDE

TABLET, EXTENDED RELEASE; ORAL

APLENZIN

+	BIOVAIL LABS INTL	174MG	N22108	001	Apr 23, 2008	Apr	NEWA
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		348MG	N22108	002	Apr 23, 2008	Apr	NEWA
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		522MG	N22108	003	Apr 23, 2008	Apr	NEWA
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BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

BUPROPION HYDROCHLORIDE

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

TABLET; ORAL

CABERGOLINE

AB	COBALT LABS INC	0.5MG	N78035	001	Apr 21, 2008	Apr	NEWA
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AB	+	PAR PHARM	0.5MG	N76310	001	Dec 29, 2005	Apr	CRLD
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DOSTINEX

@	PHARMACIA AND UPJOHN	0.5MG	N20664	001	Dec 23, 1996	Apr	DISC
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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

AT	NYCOMED US	0.005%	N78305	001	May 06, 2008	Apr	NEWA
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## SOLUTION; TOPICAL

## DOVONEX

AT	+	LEO PHARM	0.005%	N20611	001	Mar 03, 1997	Apr	CFTG
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CALCITRIOL

## INJECTABLE; INJECTION

## CALCITRIOL

AP		AKORN	0.001MG/ML	N78066	001	Jan 29, 2008	Jan	NEWA
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AP			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

## @ ROXANE

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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CANDESARTAN CILEXETIL; HYDROCHLOROTHIAZIDE

## TABLET; ORAL

## ATACAND HCT

>D>	+	ASTRAZENECA	32MG;12.5MG	N21093	002	Sep 05, 2000	May	CRLD
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>A>			32MG;12.5MG	N21093	002	Sep 05, 2000	May	CRLD
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>A>	+		32MG;25MG	N21093	003	May 16, 2008	May	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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CARBIDOPA; LEVODOPA

## TABLET; ORAL

## CARBIDOPA AND LEVODOPA

>A>	AB	APOTEX INC	10MG;100MG	N77120	001	Jun 02, 2008	May	NEWA
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>A>	AB		25MG;100MG	N77120	002	Jun 02, 2008	May	NEWA
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>A>	AB		25MG;250MG	N77120	003	Jun 02, 2008	May	NEWA
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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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TABLET; ORALCARBINOXAMINE MALEATE

>A>	AA	BOCA PHARMA	4MG	N40639 002	May 30, 2008	May	NEWA
>D>		+ MIKART	4MG	N40442 001	Mar 19, 2003	May	CTEC
>A>	AA		4MG	N40442 001	Mar 19, 2003	May	CTEC

CARBOPLATININJECTABLE; IV (INFUSION)CARBOPLATIN

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

CARISOPRODOLCAPSULE; ORALSOMA

>A>		@ MEDA PHARMS	250MG	N11792 003		May	CAHN
>D>		@ MEDPOINTE PHARM HLC	250MG	N11792 003		May	CAHN

TABLET; ORALSOMA

>A>		MEDA PHARMS	250MG	N11792 004	Sep 13, 2007	May	CAHN
>A>	AA		350MG	N11792 001		May	CAHN
>D>		MEDPOINTE PHARM HLC	250MG	N11792 004	Sep 13, 2007	May	CAHN
>D>	AA		350MG	N11792 001		May	CAHN

CEFADROXIL/CEFADROXIL HEMIHYDRATECAPSULE; ORALCEFADROXIL

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

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

CEFAZOLIN SODIUMINJECTABLE; INJECTIONKEFZOL

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 HYDROCHLORIDEINJECTABLE; INJECTIONCEFEPIME 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

CEFIXIMETABLET; ORALSUPRAX

		+ LUPIN	400MG	N65130 001	Feb 12, 2004	Apr	CMFD
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CEFPODOXIME PROXETILTABLET; ORALCEFPODOXIME PROXETIL

>A>	AB	SANDOZ	EQ 100MG BASE	N65462 001	May 28, 2008	May	NEWA
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		TABLET; ORAL							
		CEFPODOXIME PROXETIL							
>A>	AB	SANDOZ	EQ 200MG BASE	N65462	002	May 28, 2008	May	NEWA	
		<u>CEFPROZIL</u>							
		TABLET; ORAL							
		CEFPROZIL							
	AB	APOTEX INC	250MG	N65327	001	Mar 26, 2008	Mar	NEWA	
	AB		500MG	N65327	002	Mar 26, 2008	Mar	NEWA	
		<u>CEFTRIAZONE SODIUM</u>							
		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	
		<u>CEFUROXIME AXETIL</u>							
		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	
		<u>CETIRIZINE HYDROCHLORIDE</u>							
		SYRUP; ORAL							
		CERTIRIZINE HYDROCHLORIDE							
>A>	AA	TEVA PHARMS	5MG/5ML	N77279	001	May 27, 2008	May	NEWA	
		ZYRTEC							
>D>	+	MCNEIL CONSUMER	5MG/5ML	N20346	001	Sep 27, 1996	May	CFTG	
>A>	AA	+	5MG/5ML	N20346	001	Sep 27, 1996	May	CFTG	
		+	5MG/5ML	N20346	001	Sep 27, 1996	Jan	CAHN	
		<u>CHLORPHENIRAMINE MALEATE</u>							
		TABLET; ORAL							
		CHLORPHENIRAMINE MALEATE							
		@ PVT FORM	4MG	N80786	001		Apr	CAHN	
		<u>CHLORPROMAZINE HYDROCHLORIDE</u>							
		TABLET; ORAL							
		CHLORPROMAZINE HYDROCHLORIDE							
		@ PVT FORM	25MG	N80340	001		Apr	CAHN	
		@	50MG	N80340	002		Apr	CAHN	
		@	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

CICLOPIROX

GEL; TOPICAL

>A>	CICLOPIROX					
>A>	AB	NYCOMED US	0.77%	N77896 001	Jun 10, 2008	May NEWA
		LOPROX				
>D>	+	MEDICIS	0.77%	N20519 001	Jul 21, 1997	May CFTG
>A>	AB	+	0.77%	N20519 001	Jul 21, 1997	May CFTG

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

AP		CLARIS LIFESCIENCES	200MG/20ML (10MG/ML)	N78062 001	Apr 29, 2008	Apr NEWA
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
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
AB			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

CITRIC ACID; MAGNESIUM OXIDE; SODIUM CARBONATE

SOLUTION; IRRIGATION

UROLOGIC G IN PLASTIC CONTAINER

@	HOSPIRA	3.24GM/100ML;380MG/100ML;430MG/100ML	N18904	001	May 27, 1983	Apr	DISC
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CLINDAMYCIN PHOSPHATE

SOLUTION; TOPICAL

CLINDAMYCIN PHOSPHATE

@	BOCA PHARMA	EQ 1% BASE	N62930	001	Jun 28, 1989	Apr	CAHN
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CLOBETASOL PROPIONATE

AEROSOL, FOAM; TOPICAL

CLOBETASOL PROPIONATE

AB	PERRIGO ISRAEL	0.05%	N77763	001	Mar 10, 2008	Feb	NEWA
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OLUX

AB	+ CONNETICS	0.05%	N21142	001	May 26, 2000	Feb	CFTG
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CLOFIBRATE

CAPSULE; ORAL

CLOFIBRATE

>D>	AB	BANNER PHARMACAPS	500MG	N73396	001	Mar 20, 1992	May	DISC
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>A>		@	500MG	N73396	001	Mar 20, 1992	May	DISC
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>D>	AB	+ USL PHARMA	500MG	N70531	001	Jun 16, 1986	May	CTEC
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>A>		+	500MG	N70531	001	Jun 16, 1986	May	CTEC
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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
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@		100MG	N75162	002	Apr 26, 2005	Mar	DISC
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CODEINE PHOSPHATE; PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

SYRUP; ORAL

TRIACIN-C

+	ACTAVIS MID ATLANTIC	10MG/5ML;30MG/5ML;1.25MG/5ML	N88704	001	Mar 22, 1985	Feb	CRLD
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TRIPROLIDINE HCL, PSEUDOEPHEDRINE HCL AND CODEINE PHOSPHATE

@	MORTON GROVE	10MG/5ML;30MG/5ML;1.25MG/5ML	N88833	001	Nov 16, 1984	Feb	DISC
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COLCHICINE; PROBENECID

TABLET; ORAL

COL-PROBENECID

AB	+ WATSON LABS	0.5MG;500MG	N84279	001		Apr	CTEC
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PROBENECID AND COLCHICINE

AB	CONCORD LABS NJ	0.5MG;500MG	N40618	001	May 13, 2008	Apr	NEWA
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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

CROMOLYN SODIUM

SOLUTION; INHALATION

CROMOLYN SODIUM

>D>	AN	IVAX PHARMS	10MG/ML	N75271 001	Jan 18, 2000	May	CRLD
>A>	AN	+	10MG/ML	N75271 001	Jan 18, 2000	May	CRLD
		INTAL					
>D>	AN	+	KING PHARMS	10MG/ML	May 28, 1982	May	DISC
>A>		@	10MG/ML	N18596 001	May 28, 1982	May	DISC

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL

CYCLOBENZAPRINE HYDROCHLORIDE

AB		AMNEAL PHARM	10MG	N78218 001	Apr 18, 2008	Mar	NEWA
AB		RANBAXY	5MG	N78722 001	May 12, 2008	Apr	NEWA
AB			7.5MG	N78722 002	May 12, 2008	Apr	NEWA
AB			10MG	N78722 003	May 12, 2008	Apr	NEWA
		@ SANDOZ	10MG	N73683 001	Feb 26, 1993	Feb	DISC
AB		WATSON LABS	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
		@	200MG/VIAL	N88372 001	Jul 03, 1986	Jan	DISC
>A>	AP		500MG/VIAL	N40745 001	May 21, 2008	May	NEWA
		@	500MG/VIAL	N88373 001	Jul 03, 1986	Jan	DISC
>A>	AP		1GM/VIAL	N40745 002	May 21, 2008	May	NEWA
		@	1GM/VIAL	N88374 001	Sep 24, 1986	Jan	DISC
>A>	AP		2GM/VIAL	N40745 003	May 21, 2008	May	NEWA
		LYOPHILIZED CYTOXAN					
	+	BRISTOL MYERS SQUIBB	100MG/VIAL	N12142 006	Dec 05, 1985	Jan	CTEC
	+		200MG/VIAL	N12142 007	Dec 10, 1985	Jan	CTEC
>D>	+		500MG/VIAL	N12142 008	Jan 04, 1984	May	CFTG
>A>	AP	+	500MG/VIAL	N12142 008	Jan 04, 1984	May	CFTG
		+	500MG/VIAL	N12142 008	Jan 04, 1984	Jan	CTEC
>D>	+		1GM/VIAL	N12142 010	Sep 24, 1985	May	CFTG
>A>	AP	+	1GM/VIAL	N12142 010	Sep 24, 1985	May	CFTG
		+	1GM/VIAL	N12142 010	Sep 24, 1985	Jan	CTEC
>D>	+		2GM/VIAL	N12142 009	Dec 10, 1984	May	CFTG
>A>	AP	+	2GM/VIAL	N12142 009	Dec 10, 1984	May	CFTG
		+	2GM/VIAL	N12142 009	Dec 10, 1984	Jan	CTEC
		NEOSAR					
		@ TEVA PARENTERAL	100MG/VIAL	N87442 001	Feb 16, 1982	Jan	DISC
		@	200MG/VIAL	N87442 002	Feb 16, 1982	Jan	DISC
		@	500MG/VIAL	N87442 003	Feb 16, 1982	Jan	DISC
		@	1GM/VIAL	N87442 004	Jul 08, 1983	Jan	DISC
		@	2GM/VIAL	N87442 005	Mar 30, 1989	Jan	DISC

## TABLET; ORAL

## CYCLOPHOSPHAMIDE

	ROXANE	25MG	N40032 001	Aug 17, 1999	Jan	CTEC
+		50MG	N40032 002	Aug 17, 1999	Jan	CRLD
	CYTOXAN					
	@ BRISTOL MYERS SQUIBB	25MG	N12141 002		Jan	DISC
	@	50MG	N12141 001		Jan	DISC

DARUNAVIR ETHANOLATE

## TABLET; ORAL

## PREZISTA

	TIBOTEC	EQ 300MG BASE	N21976 001	Jun 23, 2006	Feb	CRLD
+		EQ 600MG BASE	N21976 002	Feb 25, 2008	Feb	NEWA

DASATINIB

## TABLET; ORAL

## SPRYCEL

>D>	+	BRISTOL MYERS SQUIBB	70MG	N21986 003	Jun 28, 2006	May	CRLD
>A>			70MG	N21986 003	Jun 28, 2006	May	CRLD
>A>	+		100MG	N21986 004	May 30, 2008	May	NEWA

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

DESMOPRESSIN ACETATE

## TABLET; ORAL

## DESMOPRESSIN ACETATE

>A>		FERRING	0.1MG	N21795 001	May 08, 2008	May	NEWA
>A>	+		0.2MG	N21795 002	May 08, 2008	May	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

	@	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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DIATRIZOATE MEGLUMINE

INJECTABLE; INJECTION

>D>							
>D>	AP	+	GE HEALTHCARE	60%	N16403 001		May DISC
>A>			@	60%	N16403 001		May DISC
			RENO-60				
>D>	AP	+	BRACCO	60%	N10040 016		May CTEC
>A>			+	60%	N10040 016		May CTEC
			SOLUTION; URETHRAL				
			CYSTOGRAFIN				
>D>	AT		BRACCO	30%	N10040 018		May CTEC
>A>				30%	N10040 018		May CTEC
>D>			HYPaque-CYSTO				
>D>	AT		GE HEALTHCARE	30%	N16403 003		May DISC
>A>			@	30%	N16403 003		May DISC

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM

INJECTABLE; INJECTION

>D>							
>D>	AP		GE HEALTHCARE	66%;10%	N86505 001		May DISC
>A>			@	66%;10%	N86505 001		May DISC

DIATRIZOATE SODIUM

>D>							
>D>							
>D>		+	GE HEALTHCARE	50%	N09561 001		May DISC
>A>			@	50%	N09561 001		May DISC

DIAZEPAM

INJECTABLE; INJECTION

DIAZEPAM

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

TABLET; ORAL

DARANIDE

>D>		@	MERCK	50MG	N11366 001		May CAHN
>A>		@	TARO	50MG	N11366 001		May CAHN

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
AT			ALCON	0.1%	N78031 001	Feb 06, 2008	Jan	NEWA

DICLOXACILLIN SODIUM

FOR SUSPENSION; ORAL

DICLOXACILLIN SODIUM

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

TABLET; ORAL

DIFLUNISAL

>D>	AB	+	TEVA	500MG	N73673 001	Jul 31, 1992	May	CRLD
>A>	AB			500MG	N73673 001	Jul 31, 1992	May	CRLD
>D>	AB		WATSON LABS	500MG	N74400 002	Jul 17, 1997	May	CRLD
>A>	AB	+		500MG	N74400 002	Jul 17, 1997	May	CRLD

DIGOXIN

INJECTABLE; INJECTION

DIGOXIN PEDIATRIC

@	HOSPIRA	0.1MG/ML	N40092 001	Apr 25, 1996	Apr	DISC
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LANOXIN PEDIATRIC

+	GLAXOSMITHKLINE	0.1MG/ML	N09330 004		Apr	CTEC
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DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

CARDIZEM CD

>D>	AB3	+	BIOVAIL	300MG	N20062 004	Dec 27, 1991	May	CRLD
>A>	AB3			300MG	N20062 004	Dec 27, 1991	May	CRLD

INJECTABLE; INJECTION

CARDIZEM

>D>	AP	+	BIOVAIL LABS INTL	5MG/ML	N20027 001	Oct 24, 1991	May	DISC
>A>		@		5MG/ML	N20027 001	Oct 24, 1991	May	DISC
>D>		+		25MG/VIAL	N20027 003	Aug 18, 1995	May	DISC
>A>		@		25MG/VIAL	N20027 003	Aug 18, 1995	May	DISC

DILTIAZEM HYDROCHLORIDE

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

CAPSULE; ORAL

DIPHENHYDRAMINE HYDROCHLORIDE

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

ELIXIR; ORAL

DIPHENHYDRAMINE HYDROCHLORIDE

@	PVT FORM	12.5MG/5ML	N85287 001		Apr	CAHN
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DIPYRIDAMOLE

TABLET; ORAL

DIPYRIDAMOLE

AB	LANNETT	25MG	N40898 001	Apr 23, 2008	Apr	NEWA
AB		50MG	N40898 002	Apr 23, 2008	Apr	NEWA
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

AB	EISAI MEDCL RES	5MG	N20690	002	Nov 25, 1996	Apr	CFTG
AB	+	10MG	N20690	001	Nov 25, 1996	Apr	CFTG

DONEPEZIL HYDROCHLORIDE

AB	TEVA	5MG	N77344	001	Apr 28, 2008	Apr	NEWA
AB		10MG	N77344	002	Apr 28, 2008	Apr	NEWA

DOXAZOSIN MESYLATE

TABLET; ORAL

DOXAZOSIN MESYLATE

>D>	AB	GENPHARM	EQ 1MG BASE	N75466	001	Oct 18, 2000	May	DISC
>A>		@	EQ 1MG BASE	N75466	001	Oct 18, 2000	May	DISC
>D>	AB		EQ 2MG BASE	N75466	002	Oct 18, 2000	May	DISC
>A>		@	EQ 2MG BASE	N75466	002	Oct 18, 2000	May	DISC
>D>	AB		EQ 4MG BASE	N75466	003	Oct 18, 2000	May	DISC
>A>		@	EQ 4MG BASE	N75466	003	Oct 18, 2000	May	DISC
>D>	AB		EQ 8MG BASE	N75466	004	Oct 18, 2000	May	DISC
>A>		@	EQ 8MG BASE	N75466	004	Oct 18, 2000	May	DISC

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

+	GALDERMA LABS LP	40MG	N50805	001	May 26, 2006	Apr	CAHN
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DOXYCYCLINE HYCLATE

CAPSULE; ORAL

DOXYCYCLINE HYCLATE

@	PVT FORM	EQ 100MG BASE	N62631	002	Jul 24, 1986	Apr	CAHN
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TABLET; ORAL

PERIOSTAT

AB	+	GALDERMA LABS LP	EQ 20MG BASE	N50783	001	Feb 02, 2001	Apr	CAHN
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DROSPIRENONE; ETHINYL ESTRADIOL

TABLET; ORAL-28

DROSPIRENONE AND ETHINYL ESTRADIOL

AB	BARR	3MG;0.03MG	N77527	001	May 09, 2008	Apr	NEWA
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YASMIN

AB	+	BAYER HLTHCARE	3MG;0.03MG	N21098	001	May 11, 2001	Apr	CFTG
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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

EDROPHONIUM CHLORIDE

INJECTABLE; INJECTION

ENLON

@ BAXTER HLTHCARE CORP 10MG/ML

N88873 001 Aug 06, 1985 Feb DISC

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HYDROCHLORIDE AND EPINEPHRINE

@ HOSPIRA

0.005MG/ML;1.5%

N89650 001 Jun 21, 1988 Apr DISC

AP 0.01MG/ML;2%

N78772 001 May 12, 2008 Apr NEWA

AP 0.02MG/ML;2%

N78772 002 May 12, 2008 Apr NEWA

XYLOCAINE W/ EPINEPHRINE

AP + DENTSPLY PHARM 0.01MG/ML;2%

N21381 001 Apr CFTG

AP + 0.02MG/ML;2%

N21381 002 Apr CFTG

EPOPROSTENOL SODIUM

INJECTABLE; INJECTION

EPOPROSTENOL SODIUM

AP TEVA PARENTERAL EQ 0.5MG BASE/VIAL

N78396 001 Apr 23, 2008 Apr NEWA

AP EQ 1.5MG BASE/VIAL

N78396 002 Apr 23, 2008 Apr NEWA

FLOLAN

AP + GLAXOSMITHKLINE EQ 0.5MG BASE/VIAL

N20444 001 Sep 20, 1995 Apr CFTG

AP + EQ 1.5MG BASE/VIAL

N20444 002 Sep 20, 1995 Apr CFTG

ERYTHROMYCIN

SWAB; TOPICAL

ERYCETTE

@ 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

@	PVT FORM	0.625MG	N83414 001	Apr	CAHN
@		1.25MG	N83765 001	Apr	CAHN
@		2.5MG	N85907 001	Apr	CAHN
FEMOGEN					
@	PVT FORM	0.625MG	N85076 001	Apr	CAHN
@		1.25MG	N85008 001	Apr	CAHN
@		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

+	WYETH PHARMS INC	250MG	N13026 002	Apr	CTNA
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ETHOSUXIMIDE

CAPSULE; ORAL

ETHOSUXIMIDE

>A>	AB	COVENANT PHARMA INC	250MG	N40686 001	May 28, 2008	May	NEWA
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ETRAVIRINE

TABLET; ORAL

INTELENCE

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

## FENOFIBRATE

AB	IMPAX LABS	160MG	N76509 002	Mar 26, 2008	Mar	NEWA
	SCIELE PHARMA INC	40MG	N22118 001	Aug 10, 2007	Apr	CAHN
	+	120MG	N22118 002	Aug 10, 2007	Apr	CAHN

FENOPROFEN CALCIUM

## CAPSULE; ORAL

## FENOPROFEN CALCIUM

>D>	AB	PAR PHARM	EQ 200MG BASE	N72437 001	Aug 22, 1988	May	DISC
>A>		@	EQ 200MG BASE	N72437 001	Aug 22, 1988	May	DISC
>D>	AB		EQ 300MG BASE	N72438 001	Aug 22, 1988	May	DISC
>A>		@	EQ 300MG BASE	N72438 001	Aug 22, 1988	May	DISC
>D>	AB	SANDOZ	EQ 200MG BASE	N72394 001	Oct 17, 1988	May	DISC
>A>		@	EQ 200MG BASE	N72394 001	Oct 17, 1988	May	DISC
>D>	AB		EQ 300MG BASE	N72395 001	Oct 17, 1988	May	DISC
>A>		@	EQ 300MG BASE	N72395 001	Oct 17, 1988	May	DISC
>D>		NALFON					
>D>	AB	+	PEDINOL	EQ 300MG BASE	N17604 002	May	DISC
>A>		@	EQ 300MG BASE	N17604 002		May	DISC
		NALFON 200					
>D>	AB		PEDINOL	EQ 200MG BASE	N17604 003	May	CRLD
>A>		+	EQ 200MG BASE	N17604 003		May	CRLD

## 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

AP	AKORN STRIDES	0.5MG/5ML(0.1MG/ML)	N78595 001	May 13, 2008	Apr	NEWA
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
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## SOLUTION; TOPICAL

## FLUOCINONIDE

	@	TARO	0.05%	N72857 001	Aug 02, 1989	Feb	DISC
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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

>D>	AB	ALPHAPHARM	EQ 10MG BASE	N75577 001	Jan 29, 2002	May	CTEC
>D>	AB		EQ 20MG BASE	N75577 002	Jan 29, 2002	May	CTEC
>D>	AB	AUROBINDO PHARMA	EQ 10MG BASE	N78619 001	Jan 31, 2008	May	CTEC
	AB		EQ 10MG BASE	N78619 001	Jan 31, 2008	Jan	NEWA
>D>	AB		EQ 20MG BASE	N78619 002	Jan 31, 2008	May	CTEC
	AB		EQ 20MG BASE	N78619 002	Jan 31, 2008	Jan	NEWA
>D>	AB		EQ 40MG BASE	N78619 003	Jan 31, 2008	May	CTNA
	AB		EQ 40MG BASE	N78619 003	Jan 31, 2008	Jan	NEWA
>D>	AB	BARR	EQ 10MG BASE	N74803 002	Jan 30, 2002	May	CTEC
>D>	AB		EQ 20MG BASE	N74803 001	Aug 02, 2001	May	CTEC
>D>	AB		EQ 40MG BASE	N76251 001	May 18, 2005	May	CTNA
>D>	AB	CARLSBAD	EQ 10MG BASE	N76022 001	Jan 30, 2002	May	CTEC
>D>	AB		EQ 20MG BASE	N76022 002	Jan 30, 2002	May	CTEC
>D>	AB	DR REDDYS LABS INC	EQ 10MG BASE	N75465 001	Jan 29, 2002	May	CTEC
>D>	AB		EQ 20MG BASE	N75465 002	Jan 29, 2002	May	CTEC
>D>	AB		EQ 40MG BASE	N75465 003	Aug 02, 2001	May	CTNA
>D>	AB	IVAX PHARMS	EQ 10MG BASE	N75245 002	Jan 31, 2002	May	CTEC
>D>	AB		EQ 20MG BASE	N75245 001	Jan 31, 2002	May	CTEC
>D>	AB		EQ 40MG BASE	N75245 003	Sep 28, 2004	May	CTNA
>D>	AB	MALLINCKRODT	EQ 10MG BASE	N75658 001	Jan 29, 2002	May	CTEC
>D>	AB		EQ 20MG BASE	N75658 002	Jan 29, 2002	May	CTEC
>D>	AB	MYLAN	EQ 10MG BASE	N75207 001	Jan 30, 2002	May	CTEC
>D>	AB		EQ 20MG BASE	N75207 002	Jan 30, 2002	May	CTEC
>D>	AB		EQ 40MG BASE	N75207 003	May 25, 2007	May	CTNA
>D>	AB	PAR PHARM	EQ 10MG BASE	N76922 001	Dec 16, 2004	May	CTEC
>D>	AB		EQ 20MG BASE	N76922 002	Dec 16, 2004	May	CTEC
>D>	AB		EQ 40MG BASE	N76922 003	Dec 16, 2004	May	CTNA
>D>	AB	PLIVA	EQ 10MG BASE	N76001 001	Jan 29, 2002	May	CTEC
>D>	AB		EQ 20MG BASE	N76001 002	Jan 29, 2002	May	CTEC
>D>	AB	RANBAXY	EQ 10MG BASE	N76165 001	Feb 01, 2002	May	CTEC
>D>	AB		EQ 20MG BASE	N76165 002	Feb 01, 2002	May	CTEC
>D>	AB		EQ 40MG BASE	N76990 001	Dec 13, 2004	May	CTNA
>D>	AB	RXELITE	EQ 10MG BASE	N75464 001	Jan 30, 2002	May	CTEC
>D>	AB		EQ 20MG BASE	N75464 002	Jan 30, 2002	May	CTEC
>D>	AB	SANDOZ	EQ 10MG BASE	N75049 001	Aug 02, 2001	May	CTEC
>D>	AB		EQ 10MG BASE	N75807 001	Jan 29, 2002	May	CTEC
>D>	AB		EQ 20MG BASE	N75807 002	Jan 29, 2002	May	CTEC
>D>	AB	TEVA	EQ 10MG BASE	N75452 001	Jan 29, 2002	May	CTEC
>D>	AB		EQ 20MG BASE	N75452 002	Jan 29, 2002	May	CTEC
>D>	AB		EQ 40MG BASE	N75452 003	Jan 29, 2002	May	CTNA
>D>	AB	WOCKHARDT	EQ 10MG BASE	N78143 001	Jan 16, 2008	May	CTEC
	AB		EQ 10MG BASE	N78143 001	Jan 16, 2008	Jan	NEWA
>D>	AB		EQ 20MG BASE	N78143 002	Jan 16, 2008	May	CTEC
	AB		EQ 20MG BASE	N78143 002	Jan 16, 2008	Jan	NEWA
>D>	AB		EQ 40MG BASE	N78143 003	Jan 16, 2008	May	CTNA

## CAPSULE; ORAL

## FLUOXETINE

	AB	WOCKHARDT	EQ 40MG BASE	N78143 003	Jan 16, 2008	Jan	NEWA
		FLUOXETINE HYDROCHLORIDE					
>A>	AB1	ALPHAPHARM	EQ 10MG BASE	N75577 001	Jan 29, 2002	May	CTEC
>A>	AB1		EQ 20MG BASE	N75577 002	Jan 29, 2002	May	CTEC
>A>	AB1	AUROBINDO PHARMA	EQ 10MG BASE	N78619 001	Jan 31, 2008	May	CTEC
>A>	AB1		EQ 20MG BASE	N78619 002	Jan 31, 2008	May	CTEC
>A>	AB		EQ 40MG BASE	N78619 003	Jan 31, 2008	May	CTNA
>A>	AB1	BARR	EQ 10MG BASE	N74803 002	Jan 30, 2002	May	CTEC
>A>	AB1		EQ 20MG BASE	N74803 001	Aug 02, 2001	May	CTEC
>A>	AB		EQ 40MG BASE	N76251 001	May 18, 2005	May	CTNA
>A>	AB1	CARLSBAD	EQ 10MG BASE	N76022 001	Jan 30, 2002	May	CTEC
>A>	AB1		EQ 20MG BASE	N76022 002	Jan 30, 2002	May	CTEC
>A>	AB1	DR REDDYS LABS INC	EQ 10MG BASE	N75465 001	Jan 29, 2002	May	CTEC
>A>	AB1		EQ 20MG BASE	N75465 002	Jan 29, 2002	May	CTEC
>A>	AB		EQ 40MG BASE	N75465 003	Aug 02, 2001	May	CTNA
>A>	AB1	IVAX PHARMS	EQ 10MG BASE	N75245 002	Jan 31, 2002	May	CTEC
>A>	AB1		EQ 20MG BASE	N75245 001	Jan 31, 2002	May	CTEC
>A>	AB		EQ 40MG BASE	N75245 003	Sep 28, 2004	May	CTNA
>A>	AB1	MALLINCKRODT	EQ 10MG BASE	N75658 001	Jan 29, 2002	May	CTEC
>A>	AB1		EQ 20MG BASE	N75658 002	Jan 29, 2002	May	CTEC
>A>	AB1	MYLAN	EQ 10MG BASE	N75207 001	Jan 30, 2002	May	CTEC
>A>	AB1		EQ 20MG BASE	N75207 002	Jan 30, 2002	May	CTEC
>A>	AB		EQ 40MG BASE	N75207 003	May 25, 2007	May	CTNA
>A>	AB1	PAR PHARM	EQ 10MG BASE	N76922 001	Dec 16, 2004	May	CTEC
>A>	AB1		EQ 20MG BASE	N76922 002	Dec 16, 2004	May	CTEC
>A>	AB		EQ 40MG BASE	N76922 003	Dec 16, 2004	May	CTNA
>A>	AB1	PLIVA	EQ 10MG BASE	N76001 001	Jan 29, 2002	May	CTEC
>A>	AB1		EQ 20MG BASE	N76001 002	Jan 29, 2002	May	CTEC
>A>	AB1	RANBAXY	EQ 10MG BASE	N76165 001	Feb 01, 2002	May	CTEC
>A>	AB1		EQ 20MG BASE	N76165 002	Feb 01, 2002	May	CTEC
>A>	AB		EQ 40MG BASE	N76990 001	Dec 13, 2004	May	CTNA
>A>	AB1	RXELITE	EQ 10MG BASE	N75464 001	Jan 30, 2002	May	CTEC
>A>	AB1		EQ 20MG BASE	N75464 002	Jan 30, 2002	May	CTEC
>A>	AB1	SANDOZ	EQ 10MG BASE	N75049 001	Aug 02, 2001	May	CTEC
>A>	AB1		EQ 10MG BASE	N75807 001	Jan 29, 2002	May	CTEC
>D>	AB		EQ 20MG BASE	N75049 002	Jan 29, 2002	May	CTEC
>A>	AB1		EQ 20MG BASE	N75049 002	Jan 29, 2002	May	CTEC
>A>	AB1		EQ 20MG BASE	N75807 002	Jan 29, 2002	May	CTEC
>A>	AB1	TEVA	EQ 10MG BASE	N75452 001	Jan 29, 2002	May	CTEC
>A>	AB2		EQ 10MG BASE	N76287 001	May 20, 2008	May	NEWA
>A>	AB1		EQ 20MG BASE	N75452 002	Jan 29, 2002	May	CTEC
>A>	AB2		EQ 20MG BASE	N76287 002	May 20, 2008	May	NEWA
>A>	AB		EQ 40MG BASE	N75452 003	Jan 29, 2002	May	CTNA
>A>	AB1	WOCKHARDT	EQ 10MG BASE	N78143 001	Jan 16, 2008	May	CTEC
>A>	AB1		EQ 20MG BASE	N78143 002	Jan 16, 2008	May	CTEC
>A>	AB		EQ 40MG BASE	N78143 003	Jan 16, 2008	May	CTNA
		PROZAC					
>D>	AB	LILLY	EQ 10MG BASE	N18936 006	Dec 23, 1992	May	CTEC
>A>	AB1		EQ 10MG BASE	N18936 006	Dec 23, 1992	May	CTEC
>D>	AB		EQ 20MG BASE	N18936 001	Dec 29, 1987	May	CTEC
>A>	AB1		EQ 20MG BASE	N18936 001	Dec 29, 1987	May	CTEC
		SARAFEM					
>D>		LILLY	EQ 10MG BASE	N18936 007	Jul 06, 2000	May	CFTG
>A>	AB2		EQ 10MG BASE	N18936 007	Jul 06, 2000	May	CFTG



CAPSULE; ORALSARAFEM

>D>	+	LILLY	EQ 20MG BASE	N18936 008	Jul 06, 2000	May	CFTG
>A>	AB2	+	EQ 20MG BASE	N18936 008	Jul 06, 2000	May	CFTG

FLUTICASONE PROPIONATESPRAY, METERED; NASALFLUTICASONE PROPIONATE

AB		HI TECH PHARMA	0.05MG/SPRAY	N77570 001	Jan 16, 2008	Jan	NEWA
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FLUVOXAMINE MALEATECAPSULE, EXTENDED RELEASE; ORALLUVOX CRSOLVAY

			100MG	N22033 001	Feb 28, 2008	Feb	NEWA
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+			150MG	N22033 002	Feb 28, 2008	Feb	NEWA
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TABLET; ORALFLUVOXAMINE MALEATE

>D>	AB		SYNTHON PHARMS	25MG	N75899 001	Jan 17, 2001	May	DISC
>A>		@		25MG	N75899 001	Jan 17, 2001	May	DISC
>D>	AB			50MG	N75899 002	Jan 17, 2001	May	DISC
>A>		@		50MG	N75899 002	Jan 17, 2001	May	DISC
>D>	AB			100MG	N75899 003	Jan 17, 2001	May	DISC
>A>		@		100MG	N75899 003	Jan 17, 2001	May	DISC

LUVOX

AB		JAZZ	25MG	N21519 001	Dec 20, 2007	Apr	CAHN
AB			50MG	N21519 002	Dec 20, 2007	Apr	CAHN
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@ HOSPIRA

			10MG/ML	N74337 001	Oct 31, 1994	Apr	DISC
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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

CAPSULE; ORAL

## GABAPENTIN

@	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

GADODIAMIDE

## INJECTABLE; INJECTION

## OMNISCAN

>D>	+	GE HEALTHCARE	14.35GM/50ML(287MG/ML)	N22066 001	Sep 05, 2007	May	DISC
>A>		@	14.35GM/50ML(287MG/ML)	N22066 001	Sep 05, 2007	May	DISC

GLIPIZIDE; METFORMIN HYDROCHLORIDE

## TABLET; ORAL

## GLIPIZIDE 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

GLUTAMINE

## FOR SOLUTION; ORAL

## NUTRESTORE

+	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

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

## 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
AB		PERRIGO CO TENNESSEE	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

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							
>A>	AB	APOTEX	12.5MG	N78389	001	May 16, 2008	May	NEWA
	AB	CADISTA PHARMS	12.5MG	N78391	001	Feb 11, 2008	Jan	NEWA

## TABLET; ORAL

	HYDROCHLOROTHIAZIDE							
>A>	AB	CARACO	12.5MG	N40857	001	May 30, 2008	May	NEWA
	@	PVT FORM	50MG	N86597	001		Apr	CAHN

HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE

## TABLET; ORAL

	INDERIDE-40/25							
>A>	AB	+ AKRIMAX PHARMS	25MG;40MG	N18031	001		May	CAHN
>D>	AB	+ WYETH PHARMS INC	25MG;40MG	N18031	001		May	CAHN
	INDERIDE-80/25							
>A>		@ AKRIMAX PHARMS	25MG;80MG	N18031	002		May	CAHN
>D>		@ WYETH PHARMS INC	25MG;80MG	N18031	002		May	CAHN
	PROPRANOLOL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE							
>D>	AB	MYLAN	25MG;80MG	N70947	001	Apr 01, 1987	May	CRLD
>A>	AB	+	25MG;80MG	N70947	001	Apr 01, 1987	May	CRLD

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OPHTHALMIC

>D>									
>D>	AT	+	MONARCH PHARMS	1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML	N50169 001			May	DISC
>A>			@	1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML	N50169 001			May	DISC
				NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE					
>D>	AT		ALCON UNIVERSAL	1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML	N62874 001	May 11, 1988		May	CRLD
>A>		+		1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML	N62874 001	May 11, 1988		May	CRLD

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

>A>	AB		HETERO DRUGS LTD	10MG	N40805 001	May 29, 2008	May	NEWA
>A>	AB			25MG	N40805 002	May 29, 2008	May	NEWA
>A>	AB			50MG	N40805 003	May 29, 2008	May	NEWA
	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
>A>	AB		SUN PHARM INDS INC	10MG	N40899 001	Jun 10, 2008	May	NEWA
>A>	AB			25MG	N40899 002	Jun 10, 2008	May	NEWA
>A>	AB			50MG	N40899 003	Jun 10, 2008	May	NEWA

IBUPROFEN

TABLET; ORAL

IBUPROFEN

			@ LEINER	300MG	N71266 001	Oct 15, 1986	Apr	DISC
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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

## TABLET; ORAL

## IMIPRAMINE HYDROCHLORIDE

AB	ACTAVIS TOTOWA	50MG	N40751 001	Feb 28, 2008	Feb	NEWA
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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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>D> IOTHALAMATE SODIUM, I-125

## &gt;D&gt; INJECTABLE; INJECTION

## &gt;D&gt; GLOFIL-125

>A>	@	ISOTEX	250-300uCi/ML	N17279 001		May	DISC
>D>		QOL MEDCL	250-300uCi/ML	N17279 001		May	DISC

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

## INJECTABLE; INJECTION

## IRINOTECAN HYDROCHLORIDE

AP	SUN PHARMA GLOBAL	40MG/2ML (20MG/ML)	N78805 001	Apr 21, 2008	Apr	NEWA
AP		100MG/5ML (20MG/ML)	N78805 002	Apr 21, 2008	Apr	NEWA
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

@	HOSPIRA	0.02MG/ML	N83283 001		Apr	DISC
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ISOSORBIDE DINITRATE

## TABLET; SUBLINGUAL

## ISOSORBIDE DINITRATE

AB	+ WATSON LABS	5MG	N86031 001	Sep 29, 1987	Jan	CRLD
	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

ISOSORBIDE MONONITRATE

## TABLET, EXTENDED RELEASE; ORAL

## &gt;D&gt; IMDUR

>D>	AB	SCHERING PLOUGH	30MG	N20225 001	Aug 12, 1993	May	DISC
>A>		@	30MG	N20225 001	Aug 12, 1993	May	DISC
>D>	AB		60MG	N20225 002	Aug 12, 1993	May	DISC
>A>		@	60MG	N20225 002	Aug 12, 1993	May	DISC
>D>	AB	+	120MG	N20225 003	Mar 30, 1995	May	DISC
>A>		@	120MG	N20225 003	Mar 30, 1995	May	DISC
		ISOSORBIDE MONONITRATE					
>D>	AB	KREMERS URBAN	120MG	N75155 003	Aug 04, 2000	May	CRLD
>A>	AB	+	120MG	N75155 003	Aug 04, 2000	May	CRLD

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

AP	+ ABBOTT ENDO	1MG/0.2ML	N19010 001	Apr 09, 1985	Apr	CAHN
	LUPRON DEPOT					
+	ABBOTT ENDO	3.75MG/VIAL	N20011 001	Oct 22, 1990	Apr	CAHN

## INJECTABLE; INJECTION

## LUPRON DEPOT

+	ABBOTT ENDO	7.5MG/VIAL	N19732 001	Jan 26, 1989	Apr	CAHN
+		22.5MG/VIAL	N20517 001	Dec 22, 1995	Apr	CAHN
LUPRON DEPOT-3						
+	ABBOTT ENDO	11.25MG/VIAL	N20708 001	Mar 07, 1997	Apr	CAHN
LUPRON DEPOT-4						
+	ABBOTT ENDO	30MG/VIAL	N20517 002	May 30, 1997	Apr	CAHN
LUPRON DEPOT-PED						
@	ABBOTT ENDO	3.75MG/VIAL, 7.5MG/VIAL	N20263 003	Apr 16, 1993	Apr	CAHN
+		7.5MG/VIAL	N20263 002	Apr 16, 1993	Apr	CAHN
@		7.5MG/VIAL, 7.5MG/VIAL	N20263 004	Apr 16, 1993	Apr	CAHN
@		3.75MG/VIAL, 7.5MG/VIAL	N20263 003	Apr 16, 1993	Apr	CAHN
+		11.25MG/VIAL	N20263 005	Jan 21, 1994	Apr	CAHN
+		15MG/VIAL	N20263 006	Jan 21, 1994	Apr	CAHN

LEVALBUTEROL HYDROCHLORIDE

## SOLUTION; INHALATION

## LEVALBUTEROL 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 DIHYDROCHLORIDE

## SOLUTION; ORAL

## XYZAL

+	UCB INC	2.5MG/5ML	N22157 001	Jan 28, 2008	Jan	NEWA
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LEVOLEUCOVORIN CALCIUM

## POWDER; IV (INFUSION)

## LEVOLEUCOVORIN

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

## INJECTABLE; INJECTION

## POLOCAINE 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; ORAL

## LEVOXYL

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 HYDROCHLORIDE

INJECTABLE; INJECTION

XYLOCAINE PRESERVATIVE FREE

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

LINDANE

LOTION; TOPICAL

LINDANE

>D>		@ ACTAVIS MID ATLANTIC	1%	N87313 001		May	CAHN
>A>		@ AL AND S	1%	N87313 001		May	CAHN

SHAMPOO; TOPICAL

LINDANE

>D>	AT	+	ACTAVIS MID ATLANTIC	1%	N87266 001	May	CAHN
>A>	AT	+	AL AND S	1%	N87266 001	May	CAHN

LITHIUM CARBONATE

CAPSULE; ORAL

ESKALITH

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; ORAL

LITHOBID

AB	+	NOVEN THERAP	300MG	N18027 001		Jan	CAHN
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LOVASTATIN

TABLET; ORAL

LOVASTATIN

AB		LUPIN	10MG	N78296 001	Mar 14, 2008	Mar	NEWA
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LUBIPROSTONE

CAPSULE; ORAL

AMITIZA

		SUCAMPO PHARMS	8UGM	N21908 002	Apr 29, 2008	Apr	NEWA
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MELOXICAM

TABLET; ORAL

MELOXICAM

		@ ROXANE	7.5MG	N77925 001	Jul 19, 2006	Feb	DISC
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		@	15MG	N77925 002	Jul 19, 2006	Feb	DISC
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MEPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION

MEPIVACAINE HYDROCHLORIDE

AP		HOSPIRA INC	3%	N40806 001	Apr 28, 2008	Apr	NEWA
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MEPROBAMATE

TABLET; ORAL

MEPROBAMATE

AA		INVAGEN PHARMS	200MG	N40797 001	Feb 27, 2008	Feb	NEWA
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## TABLET; ORAL

## MEPROBAMATE

AA	INVAGEN PHARMS	400MG	N40797 002	Feb 27, 2008	Feb	NEWA
	@ PVT FORM	400MG	N14601 001		Apr	CAHN
AA	+ WATSON LABS	400MG	N83308 001		Feb	CTEC

MESALAMINE

>A>	TABLET, DELAYED RELEASE; ORAL					
>A>	MESALAMINE					
>A>	+ PROCTOR AND GAMBLE	800MG	N21830 001	May 29, 2008	May	NEWA

METAPROTERENOL SULFATE

## SYRUP; ORAL

## METAPROTERENOL SULFATE

	@ MORTON GROVE	10MG/5ML	N74702 001	Mar 24, 1997	Feb	DISC
AA	+ SILARX	10MG/5ML	N73632 001	Jul 22, 1992	Feb	CRLD

METFORMIN HYDROCHLORIDE

## TABLET; ORAL

## METFORMIN HYDROCHLORIDE

>A>	AB	GLENMARK GENERICS	500MG	N78170 001	May 23, 2008	May	NEWA
>A>	AB		850MG	N78170 002	May 23, 2008	May	NEWA
>A>	AB		1GM	N78170 003	May 23, 2008	May	NEWA

## 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

	@ PVT FORM	2.5MG	N80970 001		Apr	CAHN
AA	+ NYCOMED US	2.5MG	N08848 001		Feb	CAHN
AA	+ NYCOMED US	5MG	N08848 002	Mar 25, 2003	Feb	CAHN

METHYLNALTREXONE BROMIDE

## SOLUTION; SUBCUTANEOUS

## RELISTOR

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

## FILM, EXTENDED RELEASE; TRANSDERMAL

## DAYTRANA

## SHIRE

	10MG/9HR (1.1MG/HR)	N21514 001	Apr 06, 2006	Apr	CRLD
	15MG/9HR (1.6MG/HR)	N21514 002	Apr 06, 2006	Apr	CRLD
	20MG/9HR (2.2MG/HR)	N21514 003	Apr 06, 2006	Apr	CRLD

METHYLTESTOSTERONE

## TABLET; BUCCAL/SUBLINGUAL

## METHYLTESTOSTERONE

	@ PVT FORM	5MG	N83836 001		Apr	CAHN
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## TABLET; ORAL

## METHYLTESTOSTERONE

	@ PVT FORM	5MG	N80214 001		Apr	CAHN
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## TABLET; ORAL

## METHYLTESTOSTERONE

@	PVT FORM	10MG	N80214 002			Apr	CAHN
@		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
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## TABLET; ORAL

## REGLAN

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

METOLAZONE

## TABLET; ORAL

## METOLAZONE

>D>	AB	WATSON LABS	10MG	N76891 001	Jul 21, 2004	May	DISC
>A>		@	10MG	N76891 001	Jul 21, 2004	May	DISC

METOPROLOL SUCCINATE

## TABLET, EXTENDED RELEASE; ORAL

## METOPROLOL SUCCINATE

AB		KV PHARM	EQ 25MG TARTRATE	N77779 001	Mar 20, 2008	Mar	NEWA
>A>	AB		EQ 50MG TARTRATE	N77176 001	May 14, 2008	May	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

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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MIDAZOLAM HYDROCHLORIDE

## INJECTABLE; INJECTION

## MIDAZOLAM HYDROCHLORIDE

>A>	AP	WOCKHARDT	EQ 1MG BASE/ML	N78141 001	May 30, 2008	May	NEWA
>A>	AP		EQ 5MG BASE/ML	N78141 002	May 30, 2008	May	NEWA

MILRINONE LACTATE

## INJECTABLE; INJECTION

## MILRINONE LACTATE IN DEXTROSE 5% IN PLASTIC CONTAINER

>A>	AP	BEDFORD LABS	EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML)	N78113 001	May 21, 2008	May	NEWA
>A>	AP		EQ 40MG BASE/200ML (EQ 0.2MG BASE/ML)	N78113 002	May 21, 2008	May	NEWA
>D>		PRIMACOR					
>D>	AP	+ SANOFI AVENTIS US	EQ 1MG BASE/ML	N19436 001	Dec 31, 1987	May	DISC
>A>		@	EQ 1MG BASE/ML	N19436 001	Dec 31, 1987	May	DISC
>D>		PRIMACOR IN DEXTROSE 5% IN PLASTIC CONTAINER					
>D>	AP	+ SANOFI AVENTIS US	EQ 20MG BASE/100ML	N20343 003	Aug 09, 1994	May	CDFR
>A>	AP	+	EQ 20MG BASE/200ML (EQ 0.2MG BASE/ML)	N20343 003	Aug 09, 1994	May	CDFR
>A>	AP	+	EQ 40MG BASE/200ML (EQ 0.2MG BASE/ML)	N20343 004	Aug 09, 1994	May	CDFR

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
AB	+	TEVA	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  
@ 10MG

N18154 001 Jan DISC  
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

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

MOEXIPRIL HYDROCHLORIDE

## TABLET; ORAL

## MOEXIPRIL HYDROCHLORIDE

>A>	AB	APOTEX INC	7.5MG	N78454 001	Jun 02, 2008	May	NEWA
>A>	AB		15MG	N78454 002	Jun 02, 2008	May	NEWA

MOMETASONE FUROATE

## CREAM; TOPICAL

## MOMETASONE FUROATE

>A>	AB	GLENMARK GENERICS	0.1%	N78541 001	May 28, 2008	May	NEWA
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POWDER; INHALATION

	MOOMETASONE FUROATE						
>A>	AB	GLENMARK GENERICS	0.1%	N78571	001	May 28, 2008	May NEWA
		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

## TABLET, EXTENDED RELEASE; ORAL

## MS CONTIN

>D>	AB	PURDUE FREDERICK	15MG	N19516	003	Sep 12, 1989	May CAHN
>D>	AB		30MG	N19516	001	May 29, 1987	May CAHN
>D>	AB	+	60MG	N19516	002	Apr 08, 1988	May CAHN
>D>	AB		100MG	N19516	004	Jan 16, 1990	May CAHN
>D>	AB		200MG	N19516	005	Nov 08, 1993	May CAHN
>A>	AB	PURDUE PHARMA LP	15MG	N19516	003	Sep 12, 1989	May CAHN
>A>	AB		30MG	N19516	001	May 29, 1987	May CAHN
>A>	AB	+	60MG	N19516	002	Apr 08, 1988	May CAHN
>A>	AB		100MG	N19516	004	Jan 16, 1990	May CAHN
>A>	AB		200MG	N19516	005	Nov 08, 1993	May CAHN

MUPIROCIN

## POWDER; INHALATION

## CENTANY

BX		ORTHONEUTROGENA	2%	N50788	001	Dec 04, 2002	Feb CAHN
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NABUMETONE

## TABLET; ORAL

## NABUMETONE

AB		INVAGEN PHARMS	500MG	N78671	001	Mar 07, 2008	Feb NEWA
AB			750MG	N78671	002	Mar 07, 2008	Feb NEWA

NAPROXEN SODIUM; SUMATRIPTAN SUCCINATE

## TABLET; ORAL

## TREXIMET

>A>	+	GLAXOSMITHKLINE	500MG;EQ 85MG BASE	N21926	001	Apr 15, 2008	May CAHN
>D>	+	POZEN	500MG;EQ 85MG BASE	N21926	001	Apr 15, 2008	May CAHN
	+		500MG;EQ 85MG BASE	N21926	001	Apr 15, 2008	Apr NEWA

NEBIVOLOL HYDROCHLORIDE

## TABLET; ORAL

## BYSTOLIC

>A>		FOREST LABS	EQ 2.5MG BASE	N21742	002	Dec 17, 2007	May CAHN
>A>			EQ 5MG BASE	N21742	003	Dec 17, 2007	May CAHN
>A>	+		EQ 10MG BASE	N21742	004	Dec 17, 2007	May CAHN
>D>		MYLAN BERTEK	EQ 2.5MG BASE	N21742	002	Dec 17, 2007	May CAHN
>D>			EQ 5MG BASE	N21742	003	Dec 17, 2007	May CAHN
>D>	+		EQ 10MG BASE	N21742	004	Dec 17, 2007	May CAHN

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

AB	EKR THERAP	20MG	N19488 001	Dec 21, 1988	Apr	CAHN
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

+	EKR THERAP	30MG	N20005 001	Feb 21, 1992	Apr	CAHN
+		45MG	N20005 002	Feb 21, 1992	Apr	CAHN
+		60MG	N20005 003	Feb 21, 1992	Apr	CAHN

INJECTABLE; INJECTION

CARDENE

+	EKR THERAP	2.5MG/ML	N19734 001	Jan 30, 1992	Apr	CAHN
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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

NITROFURAZONE

OINTMENT; TOPICAL

NITROFURAZONE

@	TARO	0.2%	N86156 001		Jan	DISC
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NYSTATIN

SUSPENSION; ORAL

NILSTAT

AA	+	GLENMARK GENERICS	100,000 UNITS/ML	N50299 001		Apr	CAHN
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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

## INJECTABLE; INJECTION

## OCTREOTIDE ACETATE

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

@ BEDFORD

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

+ ALCON

EQ 0.2% BASE

N21545 001 Dec 22, 2004 Apr CPOT

## SPRAY, METERED; NASAL

## PATANASE

+ ALCON

0.665MG/SPRAY

N21861 001 Apr 15, 2008 Apr NEWA

OMEPRAZOLE

## CAPSULE, DELAYED REL PELLETS; ORAL

## OMEPRAZOLE

>A>	AB	ANDRX PHARMS	10MG	N75347 001	May 30, 2008	May	NEWA
>A>	AB		20MG	N75347 002	May 30, 2008	May	NEWA
	AB		40MG	N75347 003	May 30, 2008	Feb	NEWA
		PRILOSEC					
>D>	+	ASTRAZENECA	40MG	N19810 002	Jan 15, 1998	May	CFTG
>A>	AB	+	40MG	N19810 002	Jan 15, 1998	May	CFTG

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

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					
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
		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

PITOCIN

>A>	AP	JHP PHARMS	100USP UNITS/10ML (10USP UNITS/ML)	N18261 002	Jul 27, 2007	May	NEWA
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INJECTABLE; INTRAMUSCULAR, IV (INFUSION)

OXYTOCIN

AP	+	BAXTER HLTHCARE CORP	100USP UNITS/10ML (10USP UNITS/ML)	N18243 002	Jan 10, 2007	Feb	NEWA
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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
AB		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

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

PERPHENAZINE

TABLET; ORAL

PERPHENAZINE

>D>	@ SANDOZ	2MG	N89683 001	Dec 08, 1988	May	CMFD
>A>	AB	2MG	N89683 001	Dec 08, 1988	May	CMFD
>D>	@	4MG	N89684 001	Dec 08, 1988	May	CMFD
>A>	AB	4MG	N89684 001	Dec 08, 1988	May	CMFD
>D>	@	8MG	N89685 001	Dec 08, 1988	May	CMFD
>A>	AB	8MG	N89685 001	Dec 08, 1988	May	CMFD
>D>	@	16MG	N89686 001	Dec 08, 1988	May	CMFD
>A>	AB	16MG	N89686 001	Dec 08, 1988	May	CMFD

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

DI-METREX

@ 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
	@ PVT FORM	35MG	N85199 001		Apr	CAHN
	@	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
AA		37.5MG	N40887 001	Apr 24, 2008	Apr	NEWA
>D>	VINTAGE PHARMS	37.5MG	N40377 001	Jan 04, 2002	May	CDFR

TABLET; ORAL

PHENTERMINE HYDROCHLORIDE

AA	KVK TECH	37.5MG	N40876 001	Mar 31, 2008	Mar	NEWA
>A>	VINTAGE PHARMS	37.5MG	N40377 001	Jan 04, 2002	May	CDFR

PHENTOLAMINE MESYLATE

INJECTABLE; INJECTION

>A>	ORAVERSE					
>A>	+ NOVALAR	0.4MG/1.7ML	N22159 001	May 09, 2008	May	NEWA

PHENYL AMINOSALICYLATE

POWDER; ORAL

PHENY-PAS-TEBAMIN

>A>	@ PHARM RES ASSOC	50%	N11695 002		May	CAHN
>D>	@ PURDUE FREDERICK	50%	N11695 002		May	CAHN

TABLET; ORAL

PHENY-PAS-TEBAMIN

>A>	@ PHARM RES ASSOC	500MG	N11695 003		May	CAHN
>D>	@ PURDUE FREDERICK	500MG	N11695 003		May	CAHN

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

CAPSULE, EXTENDED RELEASE; ORAL

MICRO-K

>D>	KV PHARM	8MEQ	N18238 001		May	CTEC
>A>	AB	8MEQ	N18238 001		May	CTEC

POTASSIUM CHLORIDE

>A>	AB	ANDRX PHARMS	8MEQ	N77419 001	Jun 02, 2008	May	NEWA
>A>	AB		10MEQ	N77419 002	Jun 02, 2008	May	NEWA

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

## TABLET; ORAL

## MIRAPEX

AB	BOEHRINGER INGELHEIM	1MG	N20667 003	Jul 01, 1997	Feb	CFTG
AB		1.5MG	N20667 005	Jul 01, 1997	Feb	CFTG

## PRAMIPEXOLE DIHYDROCHLORIDE

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
AB	ZYDUS PHARMS USA	10MG	N77751 001	Apr 30, 2008	Apr	NEWA
AB		20MG	N77751 002	Apr 30, 2008	Apr	NEWA
AB		40MG	N77751 003	Apr 30, 2008	Apr	NEWA
AB		80MG	N77751 004	Apr 30, 2008	Apr	NEWA

PREDNISOLONE

## TABLET; ORAL

## PREDNISOLONE

	@ PVT FORM	5MG	N80211 001		Apr	CAHN
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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

	+ PHARM ASSOC	EQ 10MG BASE/5ML	N78465 001	Mar 07, 2008	Apr	CRLD
AA		EQ 10MG BASE/5ML	N78465 001	Mar 07, 2008	Feb	NEWA
>A>		EQ 20MG BASE/5ML	N78988 001	Jun 09, 2008	May	NEWA

PREDNISONE

## TABLET; ORAL

## PREDNISONE

	@ PVT FORM	20MG	N85151 001		Apr	CAHN
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PRIMIDONE

## TABLET; ORAL

## PRIMIDONE

AB	AMNEAL PHARM	50MG	N40866 001	Apr 23, 2008	Apr	NEWA
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

## PROCAINAMIDE HYDROCHLORIDE

>D>	AP	HOSPIRA	100MG/ML	N89069 001	Feb 12, 1986	May	CRLD
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## INJECTABLE; INJECTION

## PROCAINAMIDE HYDROCHLORIDE

>A>	AP	+	HOSPIRA	100MG/ML	N89069 001	Feb 12, 1986	May	CRLD
>D>	AP			500MG/ML	N89070 001	Feb 12, 1986	May	CRLD
>A>	AP	+		500MG/ML	N89070 001	Feb 12, 1986	May	CRLD
>D>	AP			500MG/ML	N89537 001	Aug 25, 1987	May	DISC
>A>		@		500MG/ML	N89537 001	Aug 25, 1987	May	DISC

## PRONESTYL

## @ APOTHECON

## @

100MG/ML

N07335 002

Apr DISC

500MG/ML

N07335 005

Apr DISC

## TABLET; ORAL

## PRONESTYL

## @ APOTHECON

## @

## @

250MG

N17371 001

Apr DISC

375MG

N17371 002

Apr DISC

500MG

N17371 003

Apr DISC

PROCHLORPERAZINE EDISYLATE

## INJECTABLE; INJECTION

## PROCHLORPERAZINE EDISYLATE

## @ TEVA PARENTERAL

EQ 5MG BASE/ML

N40505 001 May 30, 2003 Jan DISC

PROMETHAZINE HYDROCHLORIDE

## INJECTABLE; INJECTION

## PROMETHAZINE HYDROCHLORIDE

AP HIKMA FARMACEUTICA

25MG/ML

N40737 001 Apr 24, 2008 Apr NEWA

AP

50MG/ML

N40737 002 Apr 24, 2008 Apr NEWA

## @ HOSPIRA

50MG/ML

N83838 002 Apr DISC

## TABLET; ORAL

## PHENERGAN

## @ WYETH PHARMS INC

25MG

N07935 003

Feb DISC

## 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

&gt;A&gt; AB

50MG

N40791 001 May 20, 2008 May NEWA

## @ PVT FORM

12.5MG

N83214 001

Apr CAHN

## @

25MG

N83658 001

Apr CAHN

AB WATSON LABS

25MG

N83426 001

Apr CTEC

AB

50MG

N83711 001

Apr CTEC

PROPANTHELINE BROMIDE

## TABLET; ORAL

## PROPANTHELINE BROMIDE

## @ PVT FORM

15MG

N80977 001

Apr CAHN

PROPOFOL

## INJECTABLE; INJECTION

## PROPOFOL

&gt;D&gt; AB BEDFORD

10MG/ML

N74848 001 Apr 19, 2005 May DISC

&gt;A&gt; @

10MG/ML

N74848 001 Apr 19, 2005 May DISC

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

PROPOXYPHENE HYDROCHLORIDE

@ PVT FORM	32MG	N83464 001		Apr	CAHN
@	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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TABLET; ORAL

INDERAL

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

PROPRANOLOL HYDROCHLORIDE

>A>	AB	IPCA LABS LTD	10MG	N78955 001	Jun 02, 2008	May	NEWA
>A>	AB		20MG	N78955 002	Jun 02, 2008	May	NEWA
>A>	AB		40MG	N78955 003	Jun 02, 2008	May	NEWA
>A>	AB		60MG	N78955 004	Jun 02, 2008	May	NEWA
>A>	AB		80MG	N78955 005	Jun 02, 2008	May	NEWA
>D>	AB	PLIVA	80MG	N71976 001	Apr 06, 1988	May	CRLD
>A>	AB +		80MG	N71976 001	Apr 06, 1988	May	CRLD
>D>	AB		90MG	N71977 001	Apr 06, 1988	May	CRLD
>A>	AB +		90MG	N71977 001	Apr 06, 1988	May	CRLD

PROTAMINE SULFATE

INJECTABLE; INJECTION

PROTAMINE SULFATE

>D>	+ ABRAXIS PHARM	10MG/ML	N89454 001	Apr 07, 1987	May	CAHN
>A>	+ APP PHARMS	10MG/ML	N89454 001	Apr 07, 1987	May	CAHN

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

TABLET; ORAL

ALLERFED

@ PVT FORM	60MG;2.5MG	N88860 001	Jan 31, 1985	Apr	CAHN
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QUETIAPINE FUMARATE

TABLET, EXTENDED RELEASE; ORAL

SEROQUEL XR

@ ASTRAZENECA	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

QUINIDINE POLYGALACTURONATE

TABLET; ORAL

CARDIOQUIN

>A>	@ PHARM RES ASSOC	275MG	N11642 002	May	CAHN
>D>	@ PURDUE FREDERICK	275MG	N11642 002	May	CAHN

RAMIPRIL

CAPSULE; ORAL

RAMIPRIL

AB	COBALT LABS INC	1.25MG	N76549 001	Oct 24, 2005	Apr	CAHN
AB		2.5MG	N76549 002	Oct 24, 2005	Apr	CAHN
AB		5MG	N76549 003	Oct 24, 2005	Apr	CAHN
AB		10MG	N76549 004	Oct 24, 2005	Apr	CAHN
>A>	AB LUPIN	1.25MG	N77626 001	Jun 09, 2008	May	NEWA
>A>	AB	2.5MG	N77626 002	Jun 09, 2008	May	NEWA
>A>	AB	5MG	N77626 003	Jun 09, 2008	May	NEWA
>A>	AB	10MG	N77626 004	Jun 09, 2008	May	NEWA

RAUWOLFIA SERPENTINA

TABLET; ORAL

RAUWOLFIA SERPENTINA

@ PVT FORM

@

50MG  
100MG

N80583 001	Apr	CAHN
N80583 002	Apr	CAHN

REGADENOSON

>D>	INJECTABLE; INJECTION					
>D>	LEXISCAN					
>D>	+ CV THERAP	0.4MG/5ML (0.08MG/ML)	N22161 001	Apr 10, 2008	May	CDFR
	+	0.4MG/5ML (0.08MG/ML)	N22161 001	Apr 10, 2008	Apr	NEWA
>A>	SOLUTION; INTRAVENOUS					
>A>	LEXISCAN					
>A>	+ CV THERAP	0.4MG/5ML (0.08MG/ML)	N22161 001	Apr 10, 2008	May	CDFR

RESERPINE

TABLET; ORAL

RESERPINE

@ PVT FORM

@

@

@

0.1MG  
0.25MG  
0.25MG  
1MG

N86117 001	Apr	CAHN
N80582 001	Apr	CAHN
N85775 001	Apr	CAHN
N80582 002	Apr	CAHN

RIBAVIRIN

TABLET; ORAL

RIBAVIRIN

ZYDUS PHARMS USA

500MG

N77094 004	Apr 18, 2008	Apr	NEWA
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RIFAMPIN

CAPSULE; ORAL

RIFAMPIN

AB LANNETT

AB

150MG  
300MG

N65390 001	Mar 28, 2008	Mar	NEWA
N65390 002	Mar 28, 2008	Mar	NEWA

INJECTABLE; INJECTION

RIFAMPIN

>A>	AP AKORN STRIDES	600MG/VIAL	N65421 001	May 22, 2008	May	NEWA
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RISEDRONATE SODIUM

TABLET; ORAL

ACTONEL

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

TABLET; ORAL

REQUIP

AB	+	GLAXOSMITHKLINE	EQ 0.25MG BASE	N20658	001	Sep 19, 1997	Apr	CFTG
AB			EQ 0.5MG BASE	N20658	002	Sep 19, 1997	Apr	CFTG
AB			EQ 1MG BASE	N20658	003	Sep 19, 1997	Apr	CFTG
AB			EQ 2MG BASE	N20658	004	Sep 19, 1997	Apr	CFTG
AB			EQ 3MG BASE	N20658	006	Jan 27, 1999	Apr	CFTG
AB			EQ 4MG BASE	N20658	007	Jan 27, 1999	Apr	CFTG
>D>			EQ 5MG BASE	N20658	005	Sep 19, 1997	May	CTEC
>A>	AB		EQ 5MG BASE	N20658	005	Sep 19, 1997	May	CTEC

ROPINIROLE HYDROCHLORIDE

>A>	AB	COREPHARMA	EQ 0.25MG BASE	N78230	001	May 20, 2008	May	NEWA
>A>	AB		EQ 0.5MG BASE	N78230	002	May 20, 2008	May	NEWA
>A>	AB		EQ 1MG BASE	N78230	003	May 20, 2008	May	NEWA
>A>	AB		EQ 2MG BASE	N78230	004	May 20, 2008	May	NEWA
>A>	AB		EQ 3MG BASE	N78230	005	May 20, 2008	May	NEWA
>A>	AB		EQ 4MG BASE	N78230	006	May 20, 2008	May	NEWA
>A>	AB		EQ 5MG BASE	N78230	007	May 20, 2008	May	NEWA
	AB	MYLAN	EQ 0.25MG BASE	N78881	001	May 05, 2008	Apr	NEWA
	AB		EQ 0.5MG BASE	N78881	002	May 05, 2008	Apr	NEWA
	AB		EQ 1MG BASE	N78881	003	May 05, 2008	Apr	NEWA
	AB		EQ 2MG BASE	N78881	004	May 05, 2008	Apr	NEWA
	AB		EQ 3MG BASE	N78881	005	May 05, 2008	Apr	NEWA
	AB		EQ 4MG BASE	N78881	006	May 05, 2008	Apr	NEWA
>A>	AB		EQ 5MG BASE	N78881	007	May 19, 2008	May	NEWA
	AB	PAR PHARM	EQ 0.25MG BASE	N78110	001	May 05, 2008	Apr	NEWA
	AB		EQ 0.5MG BASE	N78110	002	May 05, 2008	Apr	NEWA
	AB		EQ 1MG BASE	N78110	003	May 05, 2008	Apr	NEWA
	AB		EQ 2MG BASE	N78110	004	May 05, 2008	Apr	NEWA
	AB		EQ 3MG BASE	N78110	005	May 05, 2008	Apr	NEWA
	AB		EQ 4MG BASE	N78110	006	May 05, 2008	Apr	NEWA
	AB	ROXANE	EQ 0.25MG BASE	N77852	001	May 05, 2008	Apr	NEWA
	AB		EQ 0.5MG BASE	N77852	002	May 05, 2008	Apr	NEWA
	AB		EQ 1MG BASE	N77852	003	May 05, 2008	Apr	NEWA
	AB		EQ 2MG BASE	N77852	004	May 05, 2008	Apr	NEWA
	AB		EQ 3MG BASE	N77852	005	May 05, 2008	Apr	NEWA
	AB		EQ 4MG BASE	N77852	006	May 05, 2008	Apr	NEWA
>A>	AB		EQ 5MG BASE	N77852	007	May 19, 2008	May	NEWA
	AB	TEVA	EQ 0.25MG BASE	N77460	001	May 05, 2008	Apr	NEWA
	AB		EQ 0.5MG BASE	N77460	002	May 05, 2008	Apr	NEWA
	AB		EQ 1MG BASE	N77460	003	May 05, 2008	Apr	NEWA
	AB		EQ 2MG BASE	N77460	004	May 05, 2008	Apr	NEWA
	AB		EQ 3MG BASE	N77460	005	May 05, 2008	Apr	NEWA
	AB		EQ 4MG BASE	N77460	006	May 05, 2008	Apr	NEWA
>A>	AB		EQ 5MG BASE	N77460	007	May 19, 2008	May	NEWA
>A>	AB	WOCKHARDT	EQ 0.25MG BASE	N79050	001	May 29, 2008	May	NEWA
>A>	AB		EQ 0.5MG BASE	N79050	002	May 29, 2008	May	NEWA
>A>	AB		EQ 1MG BASE	N79050	003	May 29, 2008	May	NEWA
>A>	AB		EQ 2MG BASE	N79050	004	May 29, 2008	May	NEWA

TABLET; ORALROPINIROLE HYDROCHLORIDE

>A>	AB	WOCKHARDT	EQ 3MG BASE	N79050 005	May 29, 2008	May	NEWA
>A>	AB		EQ 4MG BASE	N79050 006	May 29, 2008	May	NEWA
>A>	AB		EQ 5MG BASE	N79050 007	May 29, 2008	May	NEWA

ROTIGOTINE

## FILM, EXTENDED RELEASE; TRANSDERMAL

## NEUPRO

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

SERTACONAZOLE NITRATE

## CREAM; TOPICAL

## ERTACZO

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

## TABLET; ORAL

## SERTRALINE 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

SILVER SULFADIAZINE

## CREAM; TOPICAL

## SSD

>D>	AB	BASF	1%	N18578 001	Feb 25, 1982	May	CAHN
>A>	AB	DR REDDYS LA	1%	N18578 001	Feb 25, 1982	May	CAHN

## SSD AF

>D>	BX	BASF	1%	N18578 003	Jul 11, 1990	May	CAHN
>A>	BX	DR REDDYS LA	1%	N18578 003	Jul 11, 1990	May	CAHN

SIMVASTATIN

## TABLET; ORAL

## SIMVASTATIN

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-131

## CAPSULE; ORAL

## HICON

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

## HICON

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

SODIUM LACTATE

## INJECTABLE; INJECTION

## SODIUM LACTATE 0.167 MOLAR IN PLASTIC CONTAINER

@	HOSPIRA	1.87GM/100ML	N18249 001		Apr	DISC
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SOMATROPIN RECOMBINANT

	INJECTABLE; INJECTION							
	ACCRETROPIN							
	+	CANGENE	5MG/ML (5MG/ML)	N21538	001	Jan 23, 2008	Jan	NEWA
		NORDITROPIN						
BX		NOVO NORDISK INC	5MG/1.5ML	N21148	001	Jun 20, 2000	Jan	CTEC
		NORDITROPIN NORDIFLEX						
BX		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
		OMNITROPE						
BX		SANDOZ	5MG/1.5ML	N21426	003	Jan 16, 2008	Jan	NEWA
		TEV-TROPIN						
BX	+	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

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

SULFAPHENAZOLE

	SUSPENSION; ORAL							
		SULFABID						
>A>		@ PHARM RES ASSOC	500MG/5ML	N13093	001		May	CAHN
>D>		@ PURDUE FREDERICK	500MG/5ML	N13093	001		May	CAHN

SULFASALAZINE

	TABLET; ORAL							
		SULFASALAZINE						
		@ MUTUAL PHARM	500MG	N89590	001	Oct 19, 1987	Mar	DISC



TADALAFIL

TABLET; ORAL

CIALIS

LILLY

2.5MG

N21368 004 Jan 07, 2008 Jan NEWA

>D> TECHNETIUM TC-99M GLUCEPTATE KIT

&gt;D&gt; INJECTABLE; INJECTION

&gt;D&gt; TECHNESCAN GLUCEPTATE

&gt;D&gt; DRAXIMAGE N/A

N18272 001 Jan 27, 1982 May DISC

&gt;A&gt; @ N/A

N18272 001 Jan 27, 1982 May DISC

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

TELBIVUDINE

TABLET; ORAL

TYZEKA

&gt;D&gt; + IDENIX 600MG

N22011 001 Oct 25, 2006 May CAHN

&gt;A&gt; + NOVARTIS 600MG

N22011 001 Oct 25, 2006 May CAHN

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

@ PVT FORM 250MG

N62686 001 Jul 24, 1986 Apr CAHN

@ 500MG

N62686 002 Jul 24, 1986 Apr CAHN

THALLOUS CHLORIDE, TL-201

INJECTABLE; INTRAVENOUS

THALLOUS CHLORIDE TL 201

AP MALLINCKRODT 2mCi/ML

N77698 001 Nov 09, 2006 Apr CAHN

THEOPHYLLINE

TABLET, EXTENDED RELEASE; ORAL

T-PHYL

>A>	@ PHARM RES ASSOC	200MG	N88253 001	Aug 17, 1983	May	CAHN
>D>	@ PURDUE FREDERICK	200MG	N88253 001	Aug 17, 1983	May	CAHN
	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
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TIAGABINE HYDROCHLORIDE

TABLET; ORAL

GABITRIL

>D>	+ CEPHALON	2MG	N20646 005	Apr 16, 1999	May	CRLD
>A>		2MG	N20646 005	Apr 16, 1999	May	CRLD
>D>		4MG	N20646 001	Sep 30, 1997	May	CRLD
>A>	+	4MG	N20646 001	Sep 30, 1997	May	CRLD
>D>	+	16MG	N20646 003	Sep 30, 1997	May	CRLD
>A>		16MG	N20646 003	Sep 30, 1997	May	CRLD

TIMOLOL MALEATE

SOLUTION/DROPS; OPHTHALMIC

TIMOLOL MALEATE

AT	FDC LTD	EQ 0.25% BASE	N77259 001	Apr 30, 2008	Apr	NEWA
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
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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

TORSEMIDE

INJECTABLE; INJECTION

DEMADEX

>D>	+ ROCHE	10MG/ML	N20137 002	Aug 23, 1993	May	CFTG
>A>	AP +	50MG/5ML (10MG/ML)	N20137 002	Aug 23, 1993	May	CFTG

INJECTABLE; INJECTION

>A>		TORSEMIDE						
>A>	AP	BEDFORD LABS	10MG/ML	N78007	001	Jun 11, 2008	May	NEWA
		<u>TABLET; ORAL</u>						
		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

TRAMADOL HYDROCHLORIDE

>D>		TABLET, ORALLY DISINTEGRATING; ORAL						
>D>		TRAMADOL HYDROCHLORIDE						
>D>	+	BIOVAIL	50MG	N21693	001	May 05, 2005	May	DISC
>A>	@		50MG	N21693	001	May 05, 2005	May	DISC

TRANDOLAPRIL

		<u>TABLET; ORAL</u>						
		TRANDOLAPRIL						
	AB	MYLAN	1MG	N78346	001	Apr 28, 2008	Apr	NEWA
	AB		2MG	N78346	002	Apr 28, 2008	Apr	NEWA
	AB		4MG	N78346	003	Apr 28, 2008	Apr	NEWA

TROLAMINE POLYPEPTIDE OLEATE CONDENSATE

		<u>SOLUTION/DROPS; OTIC</u>						
		CERUMENEX						
>A>	@	PHARM RES ASSOC	10%	N11340	002		May	CAHN
>D>	@	PURDUE FREDERICK	10%	N11340	002		May	CAHN

VALPROIC ACID

		<u>SYRUP; ORAL</u>						
		VALPROIC ACID						
AA		MORTON GROVE	250MG/5ML	N70868	001	Jul 01, 1986	Feb	CTNA

VARDENAFIL HYDROCHLORIDE

		<u>TABLET; ORAL</u>						
		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

		<u>INJECTABLE; INJECTION</u>						
		VECURONIUM BROMIDE						
	@	HOSPIRA	4MG/VIAL	N75558	001	Sep 11, 2001	Apr	DISC

VENLAFAXINE HYDROCHLORIDE

>A>		TABLET, EXTENDED RELEASE; ORAL						
>A>		VENLAFAXINE HYDROCHLORIDE						
>A>		OSMOTICA PHARM	EQ 37.5MG BASE	N22104	001	May 20, 2008	May	NEWA
>A>			EQ 75MG BASE	N22104	002	May 20, 2008	May	NEWA
>A>	+		EQ 150MG BASE	N22104	003	May 20, 2008	May	NEWA
>A>			EQ 225MG BASE	N22104	004	May 20, 2008	May	NEWA

VINORELBINE TARTRATE

INJECTABLE; INJECTION  
VINORELBINE TARTRATE

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

WARFARIN POTASSIUM

TABLET; ORAL

ATHROMBIN-K

>A>	@ PHARM RES ASSOC	2MG	N11771 007	May	CAHN
>A>	@	5MG	N11771 004	May	CAHN
>A>	@	10MG	N11771 005	May	CAHN
>A>	@	25MG	N11771 006	May	CAHN
>D>	@ PURDUE FREDERICK	2MG	N11771 007	May	CAHN
>D>	@	5MG	N11771 004	May	CAHN
>D>	@	10MG	N11771 005	May	CAHN
>D>	@	25MG	N11771 006	May	CAHN

WARFARIN SODIUM

TABLET; ORAL

ATHROMBIN

>A>	@ PHARM RES ASSOC	5MG	N11771 003	May	CAHN
>A>	@	10MG	N11771 002	May	CAHN
>A>	@	25MG	N11771 001	May	CAHN
>D>	@ PURDUE FREDERICK	5MG	N11771 003	May	CAHN
>D>	@	10MG	N11771 002	May	CAHN
>D>	@	25MG	N11771 001	May	CAHN

ZALEPLON

CAPSULE; ORAL

SONATA

>D>	KING PHARMS	5MG	N20859 001	Aug 13, 1999	May	CFTG
>A>	AB	5MG	N20859 001	Aug 13, 1999	May	CFTG
>D>	+	10MG	N20859 002	Aug 13, 1999	May	CFTG
>A>	AB +	10MG	N20859 002	Aug 13, 1999	May	CFTG
>A>	ZALEPLON					
>A>	AB AUROBINDO PHARMA	5MG	N78829 001	Jun 06, 2008	May	NEWA
>A>	AB	10MG	N78829 002	Jun 06, 2008	May	NEWA
>A>	AB GENPHARM	5MG	N77238 001	Jun 06, 2008	May	NEWA
>A>	AB	10MG	N77238 002	Jun 06, 2008	May	NEWA
>A>	AB ROXANE	5MG	N77237 001	Jun 06, 2008	May	NEWA
>A>	AB	10MG	N77237 002	Jun 06, 2008	May	NEWA
>A>	AB SANDOZ	5MG	N78095 001	Jun 06, 2008	May	NEWA
>A>	AB	10MG	N78095 002	Jun 06, 2008	May	NEWA
>A>	AB TEVA PHARMS	5MG	N77239 001	Jun 06, 2008	May	NEWA
>A>	AB	10MG	N77239 002	Jun 06, 2008	May	NEWA
>A>	AB UNICHEM	5MG	N78989 001	Jun 06, 2008	May	NEWA
>A>	AB	10MG	N78989 002	Jun 06, 2008	May	NEWA
>A>	AB UPSHER SMITH	5MG	N78706 001	Jun 06, 2008	May	NEWA
>A>	AB	10MG	N78706 002	Jun 06, 2008	May	NEWA

ZIDOVUDINE

TABLET; ORAL

ZIDOVUDINE

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

ZOLPIDEM TARTRATE

TABLET; ORAL

ZOLPIDEM TARTRATE

AB HIKMA

5MG

N78129 001 Apr 30, 2008 Apr NEWA

AB

10MG

N78129 002 Apr 30, 2008 Apr NEWA

OTC DRUG PRODUCT LIST - 28TH EDITION

OTC DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 5 - May 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

ACTAVIS MID ATLANTIC 5MG/5ML N90378 002 May 09, 2008 Apr NEWA

APOTEX 5MG/5ML N90188 002 Apr 22, 2008 Apr NEWA

PERRIGO R AND D 5MG/5ML N90254 002 Apr 09, 2008 Mar NEWA

RANBAXY 5MG/5ML N90183 002 Apr 24, 2008 Apr NEWA

TARO 5MG/5ML N90182 002 Apr 22, 2008 Apr NEWA

CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF

ACTAVIS MID ATLANTIC 5MG/5ML N90378 001 May 09, 2008 Apr NEWA

APOTEX 5MG/5ML N90188 001 Apr 22, 2008 Apr NEWA

PERRIGO R AND D 5MG/5ML N90254 001 Apr 09, 2008 Mar NEWA

RANBAXY 5MG/5ML N90183 001 Apr 24, 2008 Apr NEWA

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

CONTRACT PHARMA 5MG N76047 001 Dec 27, 2007 Apr CAHN

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

CETIRIZINE HYDROCHLORIDE HIVES

CONTRACT PHARMA 5MG N76047 003 Dec 27, 2007 Apr CAHN

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

ZYRTEC ALLERGY

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

+ 10MG N19835 004 Nov 16, 2007 Jan CAHN

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

IMODIUM MULTI-SYMPTOM RELIEF

+ MCNEIL	2MG;125MG	N20606	001	Jun 26, 1996	Apr	CTNA
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TABLET; ORAL

IMODIUM MULTI-SYMPTOM RELIEF

+ MCNEIL CONS	2MG;125MG	N21140	001	Nov 30, 2000	Apr	CTNA
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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

PERRIGO R AND D	EQ 2MG BASE	N78967	001	Apr 23, 2008	Apr	NEWA
	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 05 MAY 2008**

NO MAY 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 MAY 2008 ADDITIONS

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 5 - May 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	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	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	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	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>ALVIMOPAN - ENTEREG</u>						
021775	001				>A> NCE	May 20, 2013
<u>AMIFOSTINE - AMIFOSTINE</u>						
077126	001				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		

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 5 - May 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>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			
<u>ARGATROBAN - ARGATROBAN</u>						
020883 001					>A> M-75	May 05, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>						
021436 001					>A> D-115	May 06, 2011
					D-110	Oct 29, 2010
					>A> I-559	May 06, 2011
					I-555	Feb 27, 2011
					PED	Aug 27, 2011
					PED	Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>						
021436 002					>A> D-115	May 06, 2011
					D-110	Oct 29, 2010
					>A> I-559	May 06, 2011
					I-555	Feb 27, 2011
					PED	Aug 27, 2011
					PED	Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>						
021436 003					>A> D-115	May 06, 2011
					D-110	Oct 29, 2010
					>A> I-559	May 06, 2011
					I-555	Feb 27, 2011
					PED	Aug 27, 2011
					PED	Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>						
021436 004					>A> D-115	May 06, 2011
					D-110	Oct 29, 2010
					>A> I-559	May 06, 2011
					I-555	Feb 27, 2011
					PED	Aug 27, 2011
					PED	Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>						
021436 005					>A> D-115	May 06, 2011
					D-110	Oct 29, 2010
					>A> I-559	May 06, 2011
					I-555	Feb 27, 2011
					PED	Aug 27, 2011
					PED	Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>						
021436 006					>A> D-115	May 06, 2011
					D-110	Oct 29, 2010
					>A> I-559	May 06, 2011
					I-555	Feb 27, 2011
					PED	Aug 27, 2011
					PED	Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>						
021713 001					>A> D-115	May 06, 2011
					D-110	Oct 29, 2010
					>A> I-559	May 06, 2011
					I-555	Feb 27, 2011
					PED	Aug 27, 2011
					PED	Apr 29, 2011

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 5 - May 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>						
021729	002				>A> D-115 D-110 >A> I-559 I-555 PED PED	May 06, 2011 Oct 29, 2010 May 06, 2011 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>						
021729	003				>A> D-115 D-110 >A> I-559 I-555 PED PED	May 06, 2011 Oct 29, 2010 May 06, 2011 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>						
021729	004				>A> D-115 D-110 >A> I-559 I-555 PED PED	May 06, 2011 Oct 29, 2010 May 06, 2011 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>						
021729	005				>A> D-115 D-110 >A> I-559 I-555 PED PED	May 06, 2011 Oct 29, 2010 May 06, 2011 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>						
021866	001				>A> D-115 D-110 >A> I-559 I-555 PED PED	May 06, 2011 Oct 29, 2010 May 06, 2011 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>ATOMOXETINE HYDROCHLORIDE - STRATTERA</u>						
021411	001				>A> I-562	May 07, 2011
<u>ATOMOXETINE HYDROCHLORIDE - STRATTERA</u>						
021411	002				>A> I-562	May 07, 2011
<u>ATOMOXETINE HYDROCHLORIDE - STRATTERA</u>						
021411	003				>A> I-562	May 07, 2011
<u>ATOMOXETINE HYDROCHLORIDE - STRATTERA</u>						
021411	004				>A> I-562	May 07, 2011
<u>ATOMOXETINE HYDROCHLORIDE - STRATTERA</u>						
021411	005				>A> I-562	May 07, 2011

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 5 - May 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>ATOMOXETINE HYDROCHLORIDE - STRATTERA</u>						
021411 006					>A> I-562	May 07, 2011
<u>ATOMOXETINE HYDROCHLORIDE - STRATTERA</u>						
021411 007					>A> I-562	May 07, 2011
<u>ATOMOXETINE HYDROCHLORIDE - STRATTERA</u>						
021411 008					>A> I-562	May 07, 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>BETAMETHASONE DIPROPIONATE; CALCIPOTRIENE HYDRATE - TACLONEX SCALP</u>						
022185 001	>A> 6753013	Jan 27, 2020	DP U-88		>A> NDF	May 09, 2011
	>A> 6753013	Jan 27, 2020	DP U-193		>A> NC	Jan 09, 2009
	>A> 6787529	Jan 27, 2020	DP U-88			
	>A> 6787529	Jan 27, 2020	DP U-193			
	>A> RE39706	Jun 09, 2015	DS DP			
<u>BORTEZOMIB - VELCADE</u>						
021602 001	>A> 7119080	Oct 28, 2014	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 HYDROBROMIDE - APLENZIN</u>						
022108 001	>A> 7241805	Jun 27, 2026	DP			
<u>BUPROPION HYDROBROMIDE - APLENZIN</u>						
022108 002	>A> 7241805	Jun 27, 2026	DP			
<u>BUPROPION HYDROBROMIDE - APLENZIN</u>						
022108 003	>A> 7241805	Jun 27, 2026	DP			
<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				

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 5 - May 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 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				
<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 5 - May 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	6106861	Dec 05, 2017	DP			



## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 5 - May 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>CLOZAPINE - FAZACLO ODT</u>						
021590 002	6106861	Dec 05, 2017	DP			
<u>CLOZAPINE - FAZACLO ODT</u>						
021590 003	6106861	Dec 05, 2017	DP			
<u>CLOZAPINE - FAZACLO ODT</u>						
021590 004	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	5723606	Dec 15, 2019	DS DP	U-868		
	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>DASATINIB - SPRYCEL</u>						
021986 001	>A> 6596746	Jun 28, 2020	DS DP	U-780		
	>A> 6596746	Jun 28, 2020	DS DP	U-748		
<u>DASATINIB - SPRYCEL</u>						
021986 002	>A> 6596746	Jun 28, 2020	DS DP	U-780		
	>A> 6596746	Jun 28, 2020	DS DP	U-748		
<u>DASATINIB - SPRYCEL</u>						
021986 003	>A> 6596746	Jun 28, 2020	DS DP	U-780		
	>A> 6596746	Jun 28, 2020	DS DP	U-748		
<u>DASATINIB - SPRYCEL</u>						
021986 004					>A> D-109	Nov 06, 2010
					>A> M-70	Nov 06, 2010
					>A> NCE	Jun 28, 2011
					>A> ODE	Jun 28, 2013
<u>DESMOPRESSIN ACETATE - DESMOPRESSIN ACETATE</u>						
021795 001					>A> NP	May 08, 2011
<u>DESMOPRESSIN ACETATE - DESMOPRESSIN ACETATE</u>						
021795 002					>A> NP	May 08, 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			

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<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					M-74	Apr 11, 2009
<u>DEXMETHYLPHENIDATE HYDROCHLORIDE - FOCALIN XR</u>						
021802 002					M-74	Apr 11, 2009
<u>DEXMETHYLPHENIDATE HYDROCHLORIDE - FOCALIN XR</u>						
021802 003					M-74	Apr 11, 2009
<u>DEXMETHYLPHENIDATE HYDROCHLORIDE - FOCALIN XR</u>						
021802 004					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
<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	5914331	Jul 02, 2017	DS			
	5914331*PED	Jan 02, 2018				
<u>ELETRIPTAN HYDROBROMIDE - RELPAX</u>						
021016 001	>A> 5545644	Dec 26, 2016	DS DP U-876			
	6110940	Aug 29, 2017				
<u>ELETRIPTAN HYDROBROMIDE - RELPAX</u>						
021016 002	>A> 5545644	Dec 26, 2016	DS DP U-876			
	6110940	Aug 29, 2017				
<u>EMTRICITABINE - EMTRIVA</u>						
021500 001	5914331	Jul 02, 2017	DS			
	5914331*PED	Jan 02, 2018				
<u>EMTRICITABINE - EMTRIVA</u>						
021896 001	5914331	Jul 02, 2017	DS			
	5914331*PED	Jan 02, 2018				

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<u>EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE - TRUVADA</u>						
021752 001	5914331	Jul 02, 2017	DS DP U-248			
	5914331*PED	Jan 02, 2018	DS			
<u>ENFUVRTIDE - FUZEON</u>						
021481 001	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>ERLOTINIB HYDROCHLORIDE - TARCEVA</u>						
021743 001	>A> 5747498	Nov 08, 2018	DS DP U-659			
	>A> 6900221	Nov 09, 2020	DS DP U-875			
	>A> 6900221	Nov 09, 2020	DS DP U-659			
	>A> 7087613	Nov 09, 2020	U-659			
<u>ERLOTINIB HYDROCHLORIDE - TARCEVA</u>						
021743 002	>A> 5747498	Nov 08, 2018	DS DP U-659			
	>A> 6900221	Nov 09, 2020	DS DP U-875			
	>A> 6900221	Nov 09, 2020	DS DP U-659			
	>A> 7087613	Nov 09, 2020	U-659			
<u>ERLOTINIB HYDROCHLORIDE - TARCEVA</u>						
021743 003	>A> 5747498	Nov 08, 2018	DS DP U-659			
	>A> 6900221	Nov 09, 2020	DS DP U-875			
	>A> 6900221	Nov 09, 2020	DS DP U-659			
	>A> 7087613	Nov 09, 2020	U-659			
<u>ERTAPENEM SODIUM - INVANZ</u>						
021337 001	7342005	Feb 02, 2013	DP			
	7342005*PED	Aug 02, 2013				
<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			

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<u>ESOMEPRAZOLE MAGNESIUM - NEXIUM</u>						
022101 001	5690960	Nov 25, 2014	DP U-858		I-504 NPP	Oct 11, 2009 Feb 27, 2011
	5690960*PED	May 25, 2015				
	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 PED	May 23, 2009 Nov 23, 2009
	5846966*PED	Mar 21, 2014				
	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 M-58 PED PED	Oct 03, 2009 Mar 16, 2009 Apr 03, 2010 Sep 16, 2009
	5846966*PED	Mar 21, 2014				
	7229982	Dec 11, 2023	DP U-592			
	7229982*PED	Jun 11, 2024				
	RE37721	Oct 25, 2016	DS DP U-473			
	RE37721*PED	Apr 25, 2017				
<u>EZETIMIBE; SIMVASTATIN - VYTORIN</u>						
021687 002	5846966	Sep 21, 2013	DP U-593		M-60 M-58 PED PED	Oct 03, 2009 Mar 16, 2009 Apr 03, 2010 Sep 16, 2009
	5846966*PED	Mar 21, 2014				
	7229982	Dec 11, 2023	DP U-592			
	7229982*PED	Jun 11, 2024				
	RE37721	Oct 25, 2016	DS DP U-473			
	RE37721*PED	Apr 25, 2017				

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<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	5075114	Oct 23, 2010				
	5075114*PED	Nov 23, 2010				
	5667794	May 02, 2015		Y		
<u>FAMOTIDINE - PEPCID AC</u>						
020801 002	5075114	May 23, 2010	DP			
	5075114*PED	Nov 23, 2010				
	6814978	Aug 26, 2021	DP			
	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					PC	Oct 21, 2008
<u>FEXOFENADINE HYDROCHLORIDE - FEXOFENADINE HYDROCHLORIDE</u>						
077081 003					PC	Oct 21, 2008
<u>FLUOCINONIDE - VANOS</u>						
021758 001	7220424	Jan 07, 2023	U-861			
<u>FLUOXETINE HYDROCHLORIDE - FLUOXETINE HYDROCHLORIDE</u>						
076287 001					>A> PC	Nov 17, 2008
<u>FLUOXETINE HYDROCHLORIDE - FLUOXETINE HYDROCHLORIDE</u>						
076287 002					>A> PC	Nov 17, 2008
<u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u>						
021520 002	5945416	Mar 24, 2017	DS DP	Y		
<u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u>						
021520 003	5945416	Mar 24, 2017	DS DP	Y		

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<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>FLUTICASON PROPRIONATE - FLOVENT HFA</u>						
021433 001	5658549	Aug 19, 2014	DP U-710			
<u>FLUTICASON PROPRIONATE - FLOVENT HFA</u>						
021433 002	5658549	Aug 19, 2014	DP U-710			
<u>FLUTICASON PROPRIONATE - FLOVENT HFA</u>						
021433 003	5658549	Aug 19, 2014	DP U-710			
<u>FLUTICASON PROPRIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 100/50</u>						
021077 001	RE40045	Sep 07, 2010	DP		I-558	Apr 30, 2011
<u>FLUTICASON PROPRIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 250/50</u>						
021077 002	>A> 4992474	Feb 12, 2008	DS DP U-872		I-558	Apr 30, 2011
	>A> 4992474	Feb 12, 2008	DS DP U-211			
	>A> 5225445	Feb 12, 2008	U-872			
	>A> 5225445	Feb 12, 2008	U-211			
	RE40045	Sep 07, 2010	DP			
<u>FLUTICASON PROPRIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 500/50</u>						
021077 003	RE40045	Sep 07, 2010	DP		I-558	Apr 30, 2011
<u>FLUTICASON PROPRIONATE; SALMETEROL XINAFOATE - ADVAIR HFA</u>						
021254 001	RE40045	Sep 07, 2010	DP			
<u>FLUTICASON PROPRIONATE; SALMETEROL XINAFOATE - ADVAIR HFA</u>						
021254 002	RE40045	Sep 07, 2010	DP			
<u>FLUTICASON PROPRIONATE; 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	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			

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<u>GADOBENATE DIMEGLUMINE - MULTIHANCE</u>						
021357 003	4916246	Apr 10, 2012	DS			
<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 001	>A> 7358366	Apr 19, 2020	DS			
	>A> 7358366*PED	Oct 19, 2020				
<u>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</u>						
021700 002	>A> 7358366	Apr 19, 2020	DS			
	>A> 7358366*PED	Oct 19, 2020				
<u>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</u>						
021700 003	>A> 7358366	Apr 19, 2020	DS			
	>A> 7358366*PED	Oct 19, 2020				
<u>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</u>						
021700 004	5002953	Sep 17, 2011	DS DP U-840			
	>A> 7358366	Apr 19, 2020	DS			
	>A> 7358366*PED	Oct 19, 2020				
<u>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</u>						
021700 005	5002953	Sep 17, 2011	DS DP U-840			
	>A> 7358366	Apr 19, 2020	DS			
	>A> 7358366*PED	Oct 19, 2020				
<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	5635517	Oct 04, 2019	DS U-866			
<u>LENALIDOMIDE - REVLIMID</u>						
021880 002	5635517	Oct 04, 2019	DS U-866			

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<u>LENALIDOMIDE - REVLIMID</u>						
021880 003	5635517	Oct 04, 2019	DS U-866			
<u>LENALIDOMIDE - REVLIMID</u>						
021880 004	5635517	Oct 04, 2019	DS U-866			
<u>LEVALBUTEROL HYDROCHLORIDE - XOPENEX</u>						
020837 001	5362755	Mar 25, 2013	U-332			
<u>LEVALBUTEROL HYDROCHLORIDE - XOPENEX</u>						
020837 002	5362755	Mar 25, 2013	U-332			
<u>LEVALBUTEROL HYDROCHLORIDE - XOPENEX</u>						
020837 003	5362755	Mar 25, 2013	U-332			
<u>LEVALBUTEROL HYDROCHLORIDE - XOPENEX</u>						
020837 004	5362755	Mar 25, 2013	U-332			
<u>LEVETIRACETAM - KEPPRA</u>						
021035 001	>A> 4943639	Jul 14, 2008	DS			
	>A> 4943639*PED	Jan 14, 2009				
<u>LEVETIRACETAM - KEPPRA</u>						
021035 002	>A> 4943639	Jul 14, 2008	DS		>A> I-527	Mar 19, 2010
	>A> 4943639*PED	Jan 14, 2009			>A> I-506	Aug 15, 2009
					>A> NPP	Jun 21, 2008
					>A> PED	Sep 19, 2010
					>A> PED	Feb 15, 2010
					>A> PED	Dec 21, 2008
<u>LEVETIRACETAM - KEPPRA</u>						
021035 003	>A> 4943639	Jul 14, 2008	DS		>A> I-527	Mar 19, 2010
	>A> 4943639*PED	Jan 14, 2009			>A> I-506	Aug 15, 2009
					>A> NPP	Jun 21, 2008
					>A> PED	Sep 19, 2010
					>A> PED	Feb 15, 2010
					>A> PED	Dec 21, 2008
<u>LEVETIRACETAM - KEPPRA</u>						
021035 004	>A> 4943639	Jul 14, 2008	DS		>A> I-527	Mar 19, 2010
	>A> 4943639*PED	Jan 14, 2009			>A> I-506	Aug 15, 2009
					>A> NPP	Jun 21, 2008
					>A> PED	Sep 19, 2010
					>A> PED	Feb 15, 2010
					>A> PED	Dec 21, 2008
<u>LEVETIRACETAM - KEPPRA</u>						
021505 001	>A> 4943639	Jul 14, 2008	DS		>A> I-527	Mar 19, 2010
	>A> 4943639*PED	Jan 14, 2009			>A> I-506	Aug 15, 2009
					>A> NPP	Jun 21, 2008
					>A> PED	Sep 19, 2010
					>A> PED	Feb 15, 2010
					>A> PED	Dec 21, 2008
<u>LEVETIRACETAM - KEPPRA</u>						
021872 001	>A> 4943639	Jul 14, 2008	DS		>A> I-544	Aug 15, 2009
	>A> 4943639*PED	Jan 14, 2009			>A> NDF	Jul 31, 2009
					>A> PED	Feb 15, 2010
					>A> PED	Jan 31, 2010
<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					NPP	Apr 23, 2011
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
021977 002					NPP	Apr 23, 2011
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
021977 003					NPP	Apr 23, 2011
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
021977 004	7105486	Jun 29, 2023		U-842	NPP	Apr 23, 2011
	7223735	Jun 29, 2023	DP			
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
021977 005	7105486	Jun 29, 2023		U-842	NPP	Apr 23, 2011
	7223735	Jun 29, 2023	DP			
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
021977 006	7105486	Jun 29, 2023		U-842	NPP	Apr 23, 2011
	7223735	Jun 29, 2023	DP			
<u>LOPERAMIDE HYDROCHLORIDE; SIMETHICONE - IMODIUM MULTI-SYMP TOM 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				
	6284767	Feb 15, 2016		U-401		
	6284767*PED	Aug 15, 2016				
<u>LOPINAVIR; RITONAVIR - KALETRA</u>						
021251 001	5914332	Dec 13, 2015		U-351		
	5914332*PED	Jun 13, 2016				
	6284767	Feb 15, 2016		U-401		
	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				
	6284767	Feb 15, 2016	DP	U-688		
	6284767*PED	Aug 15, 2016				
	7148359	Jul 19, 2019	DP			
	7148359*PED	Jan 19, 2020				
	>A> 7364752	Nov 10, 2020	DP	U-688		

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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				
	6284767	Feb 15, 2016	DP U-688			
	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				
	>A> 7364752	Nov 10, 2020	DP U-688			
<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 001	>A> 5284858	Jul 14, 2014	DS DP			
<u>LUBIPROSTONE - AMITIZA</u>						
021908 002	>A> 5284858	Jul 14, 2014	DS DP		I-557	Apr 28, 2011
	>A> 5317032	May 31, 2011	DS DP U-874		NS	Apr 28, 2011
	>A> 6414016	Sep 05, 2020	DS DP U-874		NCE	Jan 31, 2011
	>A> 6583174	Oct 16, 2020	DS DP			
	>A> 7064148	Aug 30, 2022	DS DP U-873			
<u>MARAVIROC - SELZENTRY</u>						
022128 001	>A> 7368460	Nov 25, 2022	U-824			
<u>MARAVIROC - SELZENTRY</u>						
022128 002	>A> 7368460	Nov 25, 2022	U-824			
<u>MENTHOL; METHYL SALICYLATE - SALONPAS</u>						
022029 001					NDF NC	Feb 20, 2011 Feb 20, 2011
<u>MESALAMINE - MESALAMINE</u>						
021830 001				>A> NP		May 29, 2011

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<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		
	>A> 7358366	Apr 19, 2020	DS			
	>A> 7358366*PED	Oct 19, 2020				
<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		
	>A> 7358366	Apr 19, 2020	DS			
	>A> 7358366*PED	Oct 19, 2020				
<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		
	>A> 7358366	Apr 19, 2020	DS			
	>A> 7358366*PED	Oct 19, 2020				
<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		
	>A> 7358366	Apr 19, 2020	DS			
	>A> 7358366*PED	Oct 19, 2020				
<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		
	>A> 7358366	Apr 19, 2020	DS			
	>A> 7358366*PED	Oct 19, 2020				
<u>METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE - JANUMET</u>						
022044 001	7326708	Apr 11, 2026	DS DP U-802		M-69 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		M-69 M-68	Oct 12, 2010 Oct 12, 2010
<u>METHYLNALTREXONE BROMIDE - RELISTOR</u>						
021964 001					NCE	Apr 24, 2013

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<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	Jan 22, 2011
	>A> 6107458	Mar 16, 2019	DS DP U-845		NCE	Mar 16, 2010
	>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
<u>NAPROXEN SODIUM; SUMATRIPTAN SUCCINATE - TREXIMET</u>						
021926 001	5037845	Aug 06, 2008	DS DP U-867			
	6060499	Aug 14, 2017	DP U-867			
	6586458	Aug 14, 2017	DP U-867			
	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			

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<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
<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					M-73	Mar 03, 2011
<u>OCTREOTIDE ACETATE - SANDOSTATIN LAR</u>						
021008 002					M-73	Mar 03, 2011
<u>OCTREOTIDE ACETATE - SANDOSTATIN LAR</u>						
021008 003					M-73	Mar 03, 2011

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<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	5116863	Dec 18, 2010	DS DP		>A> NDF	Apr 15, 2011
<u>OMEPRAZOLE MAGNESIUM - PRILOSEC</u>						
022056 001	5690960	Nov 25, 2014	DP U-864		NPP	Mar 20, 2011
	5900424	May 04, 2016	DS U-864		PED	Sep 20, 2011
	6428810	Nov 03, 2019	DP U-864			
<u>OMEPRAZOLE MAGNESIUM - PRILOSEC</u>						
022056 002	5690960	Nov 25, 2014	DP U-864		NPP	Mar 20, 2011
	5900424	May 04, 2016	DS U-864		PED	Sep 20, 2011
	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
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
021610 005	5128143	Sep 19, 2008	DP		NDF	Jun 22, 2009
	5662933	Sep 09, 2013	DP			
	5958456	Sep 09, 2013	DP			
	7276250	Jul 03, 2022	DP U-826			
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
021610 006	5128143	Sep 19, 2008	DP		NDF	Jun 22, 2009
	5662933	Sep 09, 2013	DP			
	5958456	Sep 09, 2013	DP			
	7276250	Jul 03, 2022	DP U-826			
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
021610 007	5128143	Sep 19, 2008	DP		NDF	Jun 22, 2009
	5662933	Sep 09, 2013	DP			
	5958456	Sep 09, 2013	DP			
	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

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<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	7351723	Nov 17, 2021	DP			
<u>PAROXETINE HYDROCHLORIDE - PAROXETINE HYDROCHLORIDE</u>						
077873 001					>A> PC	Nov 10, 2008
<u>PAROXETINE HYDROCHLORIDE - PAROXETINE HYDROCHLORIDE</u>						
077873 002					>A> PC	Nov 10, 2008
<u>PEGAPTANIB SODIUM - MACUGEN</u>						
021756 001	6051698	May 19, 2015	DS U-622			
<u>PEMETREXED DISODIUM - ALIMTA</u>						
021462 002	5217974	Mar 29, 2011	U-551			
<u>PHENTOLAMINE MESYLATE - ORAVERSE</u>						
022159 001					>A> NP	May 09, 2011
<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			
<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>PRAMLINTIDE ACETATE - SYMLIN</u>						
021332 001	>A> 5686411	Mar 16, 2019	DS DP U-638			
	>A> 7271238	Mar 08, 2011	DS U-638			
	>A> 7271238	Mar 08, 2011	DS U-637			
<u>PRAMLINTIDE ACETATE - SYMLIN</u>						
021332 002	>A> 5686411	Mar 16, 2019	DS DP U-638			
	>A> 7271238	Mar 08, 2011	DS U-638			
	>A> 7271238	Mar 08, 2011	DS U-637			

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<u>PRAMLINTIDE ACETATE - SYMLIN</u>						
021332 003	>A> 5686411	Mar 16, 2019	DS DP U-638			
	>A> 7271238	Mar 08, 2011	DS U-638			
	>A> 7271238	Mar 08, 2011	DS U-637			
<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	6024981	Apr 09, 2018	DP			
	6221392	Apr 09, 2018	DP			
<u>PREDNISOLONE SODIUM PHOSPHATE - ORAPRED ODT</u>						
021959 002	6024981	Apr 09, 2018	DP			
	6221392	Apr 09, 2018	DP			
<u>PREDNISOLONE SODIUM PHOSPHATE - ORAPRED ODT</u>						
021959 003	6024981	Apr 09, 2018	DP			
	6221392	Apr 09, 2018	DP			
<u>PROGESTERONE - ENDOMETRIN</u>						
022057 001	7300664	Nov 17, 2019	U-856			
	7320800	Nov 17, 2019	U-856			
<u>QUETIAPINE FUMARATE - SEROQUEL</u>						
020639 001					>A> I-560	May 13, 2011
<u>QUETIAPINE FUMARATE - SEROQUEL</u>						
020639 002					>A> I-560	May 13, 2011
<u>QUETIAPINE FUMARATE - SEROQUEL</u>						
020639 003					>A> I-560	May 13, 2011
<u>QUETIAPINE FUMARATE - SEROQUEL</u>						
020639 004					>A> I-560	May 13, 2011
<u>QUETIAPINE FUMARATE - SEROQUEL</u>						
020639 005					>A> I-560	May 13, 2011
<u>QUETIAPINE FUMARATE - SEROQUEL</u>						
020639 006					>A> I-560	May 13, 2011
<u>QUETIAPINE FUMARATE - SEROQUEL</u>						
020639 007					>A> I-560	May 13, 2011
<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		



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<u>RAMIPRIL - ALTACE</u>						
019901 001	>A> 7368469	Aug 30, 2020	U-871			
<u>RAMIPRIL - ALTACE</u>						
019901 002	>A> 7368469	Aug 30, 2020	U-871			
<u>RAMIPRIL - ALTACE</u>						
019901 003	>A> 7368469	Aug 30, 2020	U-871			
<u>RAMIPRIL - ALTACE</u>						
019901 004	>A> 7368469	Aug 30, 2020	U-871			
<u>RAMIPRIL - ALTACE</u>						
022021 001	>A> 7368469	Aug 30, 2020	U-871			
<u>RAMIPRIL - ALTACE</u>						
022021 002	>A> 7368469	Aug 30, 2020	U-871			
<u>RAMIPRIL - ALTACE</u>						
022021 003	>A> 7368469	Aug 30, 2020	U-871			
<u>RAMIPRIL - ALTACE</u>						
022021 004	>A> 7368469	Aug 30, 2020	U-871			
<u>REGADENOSON - LEXISCAN</u>						
022161 001	6403567	Jun 22, 2019	DS DP U-869		NCE	Apr 10, 2013
	6642210	Jun 22, 2019	DS DP U-869			
	7144872	Jun 22, 2019	DS DP U-870			
	7144872	Jun 22, 2019	DS DP U-869			
	7144872	Jun 22, 2019	DS DP U-116			
	7183264	Jun 22, 2019	DP U-870			
	7183264	Jun 22, 2019	DP U-869			
	7183264	Jun 22, 2019	DP U-116			
<u>RISEDRONATE SODIUM - ACTONEL</u>						
020835 005	>A> 5583122	Dec 10, 2013	DS DP U-353		>A> M-52	Jan 24, 2009
	>A> 6165513	Jun 10, 2018	DP			
	>A> 7192938	May 06, 2023	U-353			
<u>RISPERIDONE - RISPERDAL</u>						
020272 001	>A> 5158952	Oct 27, 2009	U-90	Y		
	>A> 5158952*PED	Apr 27, 2010				
<u>RISPERIDONE - RISPERDAL</u>						
020272 002	>A> 5158952	Oct 27, 2009	U-90	Y		
	>A> 5158952*PED	Apr 27, 2010				
<u>RISPERIDONE - RISPERDAL</u>						
020272 003	>A> 5158952	Oct 27, 2009	U-90	Y		
	>A> 5158952*PED	Apr 27, 2010				
<u>RISPERIDONE - RISPERDAL</u>						
020272 004	>A> 5158952	Oct 27, 2009	U-90	Y		
	>A> 5158952*PED	Apr 27, 2010				
<u>RISPERIDONE - RISPERDAL</u>						
020272 005	>A> 5158952	Oct 27, 2009	U-90	Y		
	>A> 5158952*PED	Apr 27, 2010				

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<u>RISPERIDONE - RISPERDAL</u>						
020272 007	>A> 5158952	Oct 27, 2009	U-90	Y		
	>A> 5158952*PED	Apr 27, 2010				
<u>RISPERIDONE - RISPERDAL</u>						
020272 008	>A> 5158952	Oct 27, 2009	U-90	Y		
	>A> 5158952*PED	Apr 27, 2010				
<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				
<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		
	>A> 7358366	Apr 19, 2020	DS			
	>A> 7358366*PED	Oct 19, 2020				
<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		
	>A> 7358366	Apr 19, 2020	DS			
	>A> 7358366*PED	Oct 19, 2020				
<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		
	>A> 7358366	Apr 19, 2020	DS			
	>A> 7358366*PED	Oct 19, 2020				
<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					D-114	Jan 30, 2010
<u>SIROLIMUS - RAPAMUNE</u>						
021110 001	5145684	Jan 25, 2011	DP U-857		D-114	Jan 30, 2010
	5145684*PED	Jul 25, 2011				

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>SIROLIMUS - RAPAMUNE</u>						
021110 002	5145684	Jan 25, 2011	DP U-857		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			
<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	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			

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<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	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			
	RE40183	Apr 09, 2016	DS DP			
<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>VENLAFAXINE HYDROCHLORIDE - EFFEXOR XR</u>						
020699 001	>A> 6310101	Jun 28, 2013	U-46		>A> I-561	Dec 14, 2010

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>VENLAFAXINE HYDROCHLORIDE - EFFEXOR XR</u>						
020699 002	>A> 6310101	Jun 28, 2013	U-46		>A> I-561	Dec 14, 2010
<u>VENLAFAXINE HYDROCHLORIDE - EFFEXOR XR</u>						
020699 003					>A> I-561	Dec 14, 2010
<u>VENLAFAXINE HYDROCHLORIDE - EFFEXOR XR</u>						
020699 004	>A> 6310101	Jun 28, 2013	U-46		>A> I-561	Dec 14, 2010
<u>VENLAFAXINE HYDROCHLORIDE - VENLAFAXINE HYDROCHLORIDE</u>						
022104 001	>A> 6403120	Mar 20, 2017	U-839			
	>A> 6403120	Mar 20, 2017	U-535			
	>A> 6419958	Mar 20, 2017	U-839			
	>A> 6419958	Mar 20, 2017	U-535			
<u>VENLAFAXINE HYDROCHLORIDE - VENLAFAXINE HYDROCHLORIDE</u>						
022104 002	>A> 6403120	Mar 20, 2017	U-839			
	>A> 6403120	Mar 20, 2017	U-535			
	>A> 6419958	Mar 20, 2017	U-839			
	>A> 6419958	Mar 20, 2017	U-535			
<u>VENLAFAXINE HYDROCHLORIDE - VENLAFAXINE HYDROCHLORIDE</u>						
022104 003	>A> 6403120	Mar 20, 2017	U-839			
	>A> 6403120	Mar 20, 2017	U-535			
	>A> 6419958	Mar 20, 2017	U-839			
	>A> 6419958	Mar 20, 2017	U-535			
<u>VENLAFAXINE HYDROCHLORIDE - VENLAFAXINE HYDROCHLORIDE</u>						
022104 004	>A> 6403120	Mar 20, 2017	U-839			
	>A> 6403120	Mar 20, 2017	U-535			
	>A> 6419958	Mar 20, 2017	U-839			
	>A> 6419958	Mar 20, 2017	U-535			
<u>ZOLEDRONIC ACID - ZOMETA</u>						
021223 002					>A> M-61	Mar 20, 2011
					ODE	Aug 20, 2008
					>A> PED	Sep 20, 2011
					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 5 - May 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, 27<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>

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