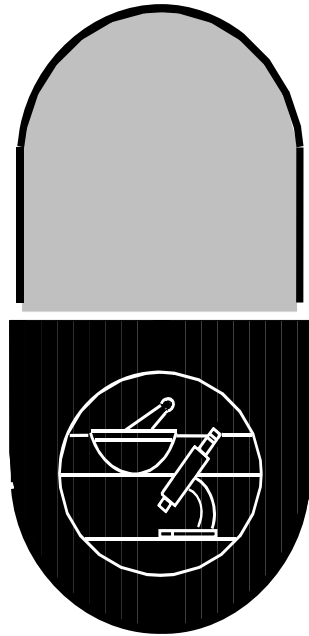


**CUMULATIVE  
SUPPLEMENT 03  
March 2008**



**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

**APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

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

**Cumulative Supplement 03**

**March 2008**

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**APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

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

**CUMULATIVE SUPPLEMENT 03  
March 2008**

**1.0 INTRODUCTION**

**1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT**

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 28th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations; over-the-counter (OTC) drug products that require approved applications as a condition of marketing; drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research; and products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

The Cumulative Supplement provides, among other things, information on newly approved drugs and, if necessary, revised therapeutic equivalence evaluations and updated patent and exclusivity data. The Addendum contains appropriate drug patent and exclusivity information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984" for the Prescription, OTC, and Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research Lists.

Because all parts of the publication are subject to changes, additions, or deletions, the List must be used in conjunction with the most current Cumulative Supplement. Users may wish to mark to the left of the ingredient(s) in the List to indicate that changes to that entry appear in the Cumulative Supplement. Drug product information is provided in each Cumulative Supplement for completeness to assist in locating the proper place in the List for the revision.

The presence of any therapeutic equivalence code indicates that the drug product is multisource; the deletion of a therapeutic equivalence code indicates that the drug product has become single source. (An infrequent exception exists when a therapeutic equivalence code is revised. In that case the deletion of the therapeutic equivalence code is followed immediately by the addition of the revised one.)

Products that have never been marketed, are for exportation, are for military use, or have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of the 27th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 28th Edition. The current edition

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

New additions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol >A>. The Patent and Exclusivity List new additions are indicated by the symbol >A> to the left of Patent Number or Exclusivity Code. The >A> symbol is then dropped in subsequent Cumulative Supplements for that item.

New deletions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol >D> (DELETE) to the left of the line. The information line with the >D> symbol is dropped in subsequent Cumulative Supplements for that item.

The Patent and Exclusivity List is arranged in alphabetical order by active ingredient name(s) and trade name. The trade name will follow the active ingredient name separated by a dash symbol. Also shown is the application number and product number (FDA's internal file number) for reference purposes. All patents with their expiration dates are displayed for each application number. Drug substance and drug product patents are indicated as such with DS or DP in the Patent codes column. Use patents are indicated with the symbol "U" followed by a number representing a specific use. Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the exclusivity expires. Refer to the Exclusivity Terms, Section B, in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations. Refer to Section 1.3 for internet access to the most current list of Patent and Exclusivity terms.

## 1.2 CUMULATIVE SUPPLEMENT CONTENT

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

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

Currently, the monthly PDF CS includes:

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

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

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

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

### 1.3 APPLICANT NAME CHANGES

It is not practical to identify in the Cumulative Supplement each and every product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name. Therefore, the cumulation of these transfers and name changes will be identified in this section only. Where only partial lines of approved products are transferred between applicants, each approved product involved will appear as an applicant name change entry in the Cumulative Supplement.

It is also not practical to identify each and every product involved when an applicant name is changed to meet internal publication standards (e.g., MSD or Zenith [Former Abbreviated Names] are changed, respectively, to Merck Sharp Dohme or Zenith Labs [New Abbreviated Names]). When this occurs, each product involved (either currently in the Cumulative Supplement or in the following year's edition) will reflect the new abbreviated name. Consequently, it will not appear as an applicant name change entry in the Cumulative Supplement nor will the cumulation of these name changes appear in this section. The Electronic Orange Book Query, updated monthly, will contain the most current applicant holder name.

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

### 1.4 AVAILABILITY OF THE EDITION

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

Query provides searching of the approved drug list by active ingredient, proprietary name, applicant holder, applicant number or patent number. Product search categories are: prescription, over-the-counter, discontinued drugs. There are links to patent and exclusivity information that may be applicable to each product.

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

The downloaded Annual Edition and Cumulative Supplements are also available in a paper version (Approved Drug Products with Therapeutic Equivalence Evaluations, ADP) from the U.S. Government Printing Office: [http://bookstore.gpo.gov/;](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 3 - March 2008

1-1

ACEBUTOLOL HYDROCHLORIDE

CAPSULE; ORAL

ACEBUTOLOL HYDROCHLORIDE

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

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

@	MUTUAL PHARM	300MG;15MG	N89671 001	Feb 10, 1988	Feb	DISC
---	--------------	------------	------------	--------------	-----	------

ACETAMINOPHEN; HYDROCODONE BITARTRATE

SOLUTION; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

@	MIKART	500MG/15ML;5MG/15ML	N89557 001	Apr 29, 1992	Feb	DISC
---	--------	---------------------	------------	--------------	-----	------

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
---	------	-------	------------	--------------	-----	------

@		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
---	-------------	-------------	------------	--------------	-----	------

ALENDRONATE SODIUM

TABLET; ORAL

ALENDRONATE SODIUM

AB	BARR	EQ 70MG BASE	N76184 001	Feb 06, 2008	Jan	NEWA
AB	TEVA PHARMS	EQ 5MG BASE	N75710 001	Feb 06, 2008	Jan	NEWA
AB		EQ 10MG BASE	N75710 002	Feb 06, 2008	Jan	NEWA
AB		EQ 35MG BASE	N75710 003	Feb 06, 2008	Jan	NEWA
AB		EQ 40MG BASE	N75710 004	Feb 06, 2008	Jan	NEWA
AB		EQ 70MG BASE	N75710 005	Feb 06, 2008	Jan	NEWA
FOSAMAX						
AB	MERCK AND CO INC	EQ 5MG BASE	N20560 003	Apr 25, 1997	Jan	CFTG
AB		EQ 10MG BASE	N20560 001	Sep 29, 1995	Jan	CFTG
AB		EQ 35MG BASE	N20560 004	Oct 20, 2000	Jan	CFTG
AB		EQ 40MG BASE	N20560 002	Sep 29, 1995	Jan	CFTG
AB	+	EQ 70MG BASE	N20560 005	Oct 20, 2000	Jan	CFTG

ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

TEKTURNA HCT

NOVARTIS

		EQ 150MG BASE;12.5MG	N22107 001	Jan 18, 2008	Jan	NEWA
		EQ 150MG BASE;25MG	N22107 002	Jan 18, 2008	Jan	NEWA
		EQ 300MG BASE;12.5MG	N22107 003	Jan 18, 2008	Jan	NEWA
	+	EQ 300MG BASE;25MG	N22107 004	Jan 18, 2008	Jan	NEWA

ALOSETRON HYDROCHLORIDE

TABLET; ORAL

LOTRONEX

>D>	GLAXOSMITHKLINE	EQ 0.5MG BASE	N21107 002	Dec 23, 2003	Mar	CAHN
>D>	+	EQ 1MG BASE	N21107 001	Feb 09, 2000	Mar	CAHN
>A>	PROMETHEUS LABS	EQ 0.5MG BASE	N21107 002	Dec 23, 2003	Mar	CAHN
>A>	+	EQ 1MG BASE	N21107 001	Feb 09, 2000	Mar	CAHN

ALPRAZOLAM

TABLET; ORAL

ALPRAZOLAM

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

AMANTADINE HYDROCHLORIDE

SYRUP; ORAL

AMANTADINE HYDROCHLORIDE

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

AMIFOSTINE

INJECTABLE; INJECTION

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

AMIODARONE HYDROCHLORIDE

INJECTABLE; INJECTION

AMIODARONE HYDROCHLORIDE

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
--	--------	-------	--------	-----	--------------	-----	------

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
---	--------------------	-------	--------	-----	--------------	-----	------

ATENOLOL

INJECTABLE; INJECTION

TENORMIN

	@ ASTRAZENECA	0.5MG/ML	N19058	001	Sep 13, 1989	Feb	DISC
--	---------------	----------	--------	-----	--------------	-----	------

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; EDROPHONIUM CHLORIDE

INJECTABLE; INJECTION

ENLON-PLUS

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

AZITHROMYCIN

TABLET; ORAL

AZITHROMYCIN

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

## TABLET; ORAL

## AZITHROMYCIN

AB	WOCKHARDT	EQ 600MG BASE	N65302 003	Feb 11, 2008	Jan	NEWA
----	-----------	---------------	------------	--------------	-----	------

AZTREONAM

## INJECTABLE; INJECTION

## AZACTAM

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

>A> BENDAMUSTINE HYDROCHLORIDE

## &gt;A&gt; POWDER; IV (INFUSION)

## &gt;A&gt; TREANDA

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

BENDROFLUMETHIAZIDE; NADOLOL

## TABLET; ORAL

## NADOLOL AND BENDROFLUMETHAZIDE

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

AB		5MG;80MG	N78688 002	Feb 15, 2008	Feb	NEWA
----	--	----------	------------	--------------	-----	------

BENZONATATE

## CAPSULE; ORAL

## BENZONATATE

AA	ORIT LABS LLC	100MG	N40682 001	Jul 30, 2007	Jan	CAHN
----	---------------	-------	------------	--------------	-----	------

AA		200MG	N40682 002	Jul 30, 2007	Jan	CAHN
----	--	-------	------------	--------------	-----	------

>A>	AA	SUN PHARM INDS INC	100MG	N40587 001	Mar 19, 2008	Mar	NEWA
-----	----	--------------------	-------	------------	--------------	-----	------

>A>	AA		200MG	N40587 002	Mar 19, 2008	Mar	NEWA
-----	----	--	-------	------------	--------------	-----	------

BENZTROPINE MESYLATE

## TABLET; ORAL

## BENZTROPINE MESYLATE

AA	ACTAVIS TOTOWA	0.5MG	N40699 001	Feb 14, 2008	Jan	NEWA
----	----------------	-------	------------	--------------	-----	------

AA		1MG	N40705 001	Feb 14, 2008	Jan	NEWA
----	--	-----	------------	--------------	-----	------

AA		2MG	N40706 001	Feb 14, 2008	Jan	NEWA
----	--	-----	------------	--------------	-----	------

	@ MUTUAL PHARM	1MG	N81264 001	Jan 23, 1992	Feb	DISC
--	----------------	-----	------------	--------------	-----	------

	@	2MG	N81265 001	Jan 23, 1992	Feb	DISC
--	---	-----	------------	--------------	-----	------

BETHANECHOL CHLORIDE

## TABLET; ORAL

## BETHANECHOL CHLORIDE

>A>	AA	LANNETT	5MG	N40703 001	Mar 27, 2008	Mar	NEWA
-----	----	---------	-----	------------	--------------	-----	------

>A>	AA		10MG	N40704 001	Mar 27, 2008	Mar	NEWA
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>A>	AA		25MG	N40678 003	Mar 27, 2008	Mar	NEWA
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>A>	AA		50MG	N40677 001	Mar 27, 2008	Mar	NEWA
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BLEOMYCIN SULFATE

## INJECTABLE; INJECTION

## BLEOMYCIN SULFATE

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

## BLEOMYCIN SULFATE

AP	TEVA PARENTERAL	EQ 30 UNITS BASE/VIAL	N65033 002	Jun 27, 2000	Jan	CTNA
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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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BUPROPION HYDROCHLORIDE

## TABLET, EXTENDED RELEASE; ORAL

## BUPROPION HYDROCHLORIDE

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

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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CALCITRIOL

## INJECTABLE; INJECTION

## CALCITRIOL

AP	AKORN	0.001MG/ML	N78066 001	Jan 29, 2008	Jan	NEWA
AP		0.002MG/ML	N78066 002	Jan 29, 2008	Jan	NEWA

CALCIUM ACETATE

## CAPSULE; ORAL

## CALCIUM ACETATE

AB	ROXANE	EQ 169MG CALCIUM	N77728 001	Feb 26, 2008	Feb	NEWA
AB	+ FRESenius MEDCL	EQ 169MG CALCIUM	N21160 003	Apr 02, 2001	Feb	CFTG
	PHOSLO GELCAPS					
	TABLET; ORAL					
	CALCIUM ACETATE					
	+ ROXANE	EQ 169MG CALCIUM	N77693 001	Jan 30, 2008	Jan	NEWA

CAPTOPRIL

## TABLET; ORAL

## CAPTOPRIL

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

## TABLET; ORAL

## CAPTOPRIL

@	WATSON LABS	25MG	N74576 002	Apr 23, 1996	Feb	DISC
@		50MG	N74576 003	Apr 23, 1996	Feb	DISC
@		100MG	N74576 004	Apr 23, 1996	Feb	DISC

CARBINOXAMINE MALEATE

## SOLUTION; ORAL

## CARBINOXAMINE MALEATE

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

CEFADROXIL/CEFADROXIL HEMIHYDRATE

## CAPSULE; ORAL

## CEFADROXIL

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

## CEFADROXIL

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

CEFAZOLIN SODIUM

## INJECTABLE; INJECTION

## KEFZOL

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

CEFEPIME HYDROCHLORIDE

## INJECTABLE; INJECTION

## CEFEPIME HYDROCHLORIDE

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

CEFPROZIL

## TABLET; ORAL

## CEFPROZIL

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

CEFTRIAZONE SODIUM

## INJECTABLE; IM-IV

## CEFTRIAZONE

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

CEFUROXIME AXETIL

## FOR SUSPENSION; ORAL

## CEFTIN

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

## FOR SUSPENSION; ORAL

## CEFUROXIME AXETIL

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

## TABLET; ORAL

## CEFUROXIME AXETIL

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

CETIRIZINE HYDROCHLORIDE

## SYRUP; ORAL

## ZYRTEC

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

## AEROSOL, METERED; INHALATION

## ALVESCO

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

CIPROFLOXACIN

## INJECTABLE; INJECTION

## CIPRO IN DEXTROSE 5% IN PLASTIC CONTAINER

>D>	+	BAYER PHARMS	200MG/100ML	N19857 001	Dec 26, 1990	Mar	CFTG
>A>	AP	+	200MG/100ML	N19857 001	Dec 26, 1990	Mar	CFTG
>A>	AP	+	400MG/200ML	N19857 002	Dec 26, 1990	Mar	CFTG

## CIPROFLOXACIN IN DEXTROSE 5% IN PLASTIC CONTAINER

>A>	AP	ACS DOBFAR INFO SA	200MG/100ML	N78252 001	Mar 18, 2008	Mar	NEWA
>A>	AP		400MG/200ML	N78252 002	Mar 18, 2008	Mar	NEWA
>A>	AP	BAXTER HLTHCARE	200MG/100ML	N77888 001	Mar 18, 2008	Mar	NEWA
>A>	AP		400MG/200ML	N77888 002	Mar 18, 2008	Mar	NEWA
>A>	AP	BEDFORD	200MG/100ML	N78114 001	Mar 18, 2008	Mar	NEWA
>A>	AP		400MG/200ML	N78114 002	Mar 18, 2008	Mar	NEWA
>A>	AP	CLARIS LIFESCIENCES	200MG/100ML	N78024 001	Mar 18, 2008	Mar	NEWA
>A>	AP		400MG/200ML	N78024 002	Mar 18, 2008	Mar	NEWA
>A>	AP	HOSPIRA	200MG/100ML	N77753 001	Mar 18, 2008	Mar	NEWA
>A>	AP		400MG/200ML	N77753 002	Mar 18, 2008	Mar	NEWA
>A>	AP	TEVA PARENTERAL	200MG/100ML	N77138 001	Mar 18, 2008	Mar	NEWA
>A>	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

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



## TABLET; ORAL

## CITALOPRAM HYDROBROMIDE

>A>	AB	NATCO PHARMA LTD	EQ 40MG BASE	N77141	001	Apr 10, 2008	Mar	NEWA
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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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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

>D>	AB	TEVA	25MG	N75162	001	Apr 26, 2005	Mar	DISC
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>A>		@	25MG	N75162	001	Apr 26, 2005	Mar	DISC
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>D>	AB		100MG	N75162	002	Apr 26, 2005	Mar	DISC
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>A>		@	100MG	N75162	002	Apr 26, 2005	Mar	DISC
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CODEINE PHOSPHATE; PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

## SYRUP; ORAL

## TRIAFIN-C

+		ACTAVIS MID ATLANTIC	10MG/5ML;30MG/5ML;1.25MG/5ML	N88704	001	Mar 22, 1985	Feb	CRLD
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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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COLISTIMETHATE

## INJECTABLE; INJECTION

## COLISTIMETHATE

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

## SOLUTION; INTRAVENOUS

## COSYNTROPIN

		SANDOZ	0.25MG/ML (0.25MG/ML)	N22028	001	Feb 21, 2008	Feb	NEWA
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CYCLOBENZAPRINE HYDROCHLORIDE

## TABLET; ORAL

## CYCLOBENZAPRINE HYDROCHLORIDE

>A>	AB	AMNEAL PHARM	10MG	N78218	001	Apr 18, 2008	Mar	NEWA
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		@ SANDOZ	10MG	N73683	001	Feb 26, 1993	Feb	DISC
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		@ WATSON LABS	10MG	N73143	001	Nov 27, 1991	Feb	DISC
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		@	10MG	N74436	001	Nov 30, 1994	Feb	DISC
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CYCLOPHOSPHAMIDE

## INJECTABLE; INJECTION

## CYCLOPHOSPHAMIDE

@		BAXTER HLTHCARE	100MG/VIAL	N88371	001	Jul 03, 1986	Jan	DISC
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@			200MG/VIAL	N88372	001	Jul 03, 1986	Jan	DISC
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@			500MG/VIAL	N88373	001	Jul 03, 1986	Jan	DISC
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@			1GM/VIAL	N88374	001	Sep 24, 1986	Jan	DISC
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## INJECTABLE; INJECTION

## LYOPHILIZED CYTOXAN

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

## NEOSAR

@	TEVA PARENTERAL	100MG/VIAL	N87442 001	Feb 16, 1982	Jan	DISC
@		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

DEMECLOCYCLINE HYDROCHLORIDE

## TABLET; ORAL

## DEMECLOCYCLINE HYDROCHLORIDE

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

DESVENLAFAXINE SUCCINATE

## TABLET, EXTENDED RELEASE; ORAL

## PRISTIQ

	WYETH PHARMS INC	EQ 50MG BASE	N21992 001	Feb 29, 2008	Feb	NEWA
+		EQ 100MG BASE	N21992 002	Feb 29, 2008	Feb	NEWA

DEXAMETHASONE

## ELIXIR; ORAL

## DEXAMETHASONE

AA	+	MORTON GROVE	0.5MG/5ML	N88254 001	Jul 27, 1983	Feb	CTNA
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DEXCHLORPHENIRAMINE MALEATE

## SYRUP; ORAL

## DEXCHLORPHENIRAMINE MALEATE

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

## DEXCHLORPHENIRAMINE MALEATE

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

## SOLUTION; ORAL

## DEXTROAMPHETAMINE SULFATE

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

INJECTABLE; INJECTION

DIAZEPAM

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

GEL; TOPICAL

SOLARAZE

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

DICLOFENAC SODIUM

>A> 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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DILTIAZEM HYDROCHLORIDE

INJECTABLE; INJECTION

DILTIAZEM HYDROCHLORIDE

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

CAPSULE; ORAL

DIPHENHYDRAMINE HYDROCHLORIDE

@ MUTUAL PHARM	25MG	N84506 001		Feb	DISC
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@	25MG	N89488 001	Jan 02, 1987	Feb	DISC
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DIPYRIDAMOLE

TABLET; ORAL

DIPYRIDAMOLE

AB	ZYDUS PHARMS USA INC	25MG	N40874 001	Jan 28, 2008	Jan	NEWA
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AB		50MG	N40874 002	Jan 28, 2008	Jan	NEWA
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AB		75MG	N40874 003	Jan 28, 2008	Jan	NEWA
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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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DOXEPIN HYDROCHLORIDE

CREAM; TOPICAL

ZONALON

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

INJECTABLE; INJECTION

ENLON

@	BAXTER HLTHCARE CORP	10MG/ML	N88873	001	Aug 06, 1985	Feb	DISC
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ERYTHROMYCIN

SWAB; TOPICAL

ERYCETTE

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

FOR SUSPENSION, DELAYED RELEASE; ORAL

NEXIUM

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

GEL, METERED; TRANSDERMAL

ELESTRIN

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

+	ASCEND	0.06% (1.25GM/ACTIVATION)	N21166	002	Feb 09, 2004	Jan	CTEC
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ESTRADIOL; NORETHINDRONE ACETATE

TABLET; ORAL

ACTIVELLA

>D>	+	NOVO NORDISK INC	1MG;0.5MG	N20907	001	Nov 18, 1998	Mar	CFTG
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>A>	AB	+		N20907	001	Nov 18, 1998	Mar	CFTG
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>A>		ESTRADIOL AND NORETHIDRONE ACETATE						
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>A>	AB	BRECKENRIDGE PHARM	1MG;0.5MG	N78324	001	Apr 17, 2008	Mar	NEWA
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ETHAMBUTOL HYDROCHLORIDE

TABLET; ORAL

MYAMBUTOL

AB		STAT-TRADE	100MG	N16320	001		Jan	CAHN
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	@		200MG	N16320	002		Jan	CAHN
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AB			400MG	N16320	003		Jan	CAHN
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	@		500MG	N16320	004		Jan	CAHN
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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
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@	HOSPIRA	10MG/ML	N75905	001	Nov 23, 2001	Feb	DISC
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## TABLET; ORAL

## FAMOTIDINE

@ SANDOZ 20MG  
@ 40MG

N75793 001 Apr 16, 2001 Feb DISC  
N75793 002 Apr 16, 2001 Feb DISC

FELODIPINE

## TABLET, EXTENDED RELEASE; ORAL

## FELODIPINE

>A> AB MYLAN 2.5MG  
>A> AB 5MG  
>A> AB 10MG

N78855 001 Apr 17, 2008 Mar NEWA  
N78855 002 Apr 17, 2008 Mar NEWA  
N78855 003 Apr 17, 2008 Mar NEWA

FENOFIBRATE

## TABLET; ORAL

## FENOFIBRATE

>A> AB IMPAX LABS 54MG  
>A> AB 160MG

N76509 001 Mar 26, 2008 Mar NEWA  
N76509 002 Mar 26, 2008 Mar NEWA

FENOPROFEN CALCIUM

## TABLET; ORAL

## FENOPROFEN CALCIUM

@ WATSON LABS EQ 600MG BASE  
@ EQ 600MG BASE

N72407 001 Aug 17, 1988 Feb DISC  
N72602 001 Oct 11, 1988 Feb DISC

FEXOFENADINE HYDROCHLORIDE

## TABLET; ORAL

## FEXOFENADINE HYDROCHLORIDE

>A> AB MYLAN 30MG  
>A> AB 60MG

N77081 002 Apr 11, 2008 Mar NEWA  
N77081 003 Apr 11, 2008 Mar NEWA

FLECAINIDE ACETATE

## TABLET; ORAL

## FLECAINIDE ACETATE

AB AMNEAL PHARM 50MG  
AB 100MG  
AB 150MG

N75442 001 Jul 31, 2001 Feb CAHN  
N75442 002 Jul 31, 2001 Feb CAHN  
N75442 003 Jul 31, 2001 Feb CAHN

FLUOCINONIDE

## CREAM; TOPICAL

## FLUOCINONIDE

@ TARO 0.05%

N71500 001 Jun 10, 1987 Feb DISC

## SOLUTION; TOPICAL

## FLUOCINONIDE

@ TARO 0.05%

N72857 001 Aug 02, 1989 Feb DISC

FLUOROURACIL

## CREAM; TOPICAL

## EFUDEX

>D> + VALEANT PHARM INTL 5%  
>A> AB + 5%  
>A> FLUOROURACIL  
>A> AB SPEAR PHARMS 5%

N16831 003 Mar CFTG  
N16831 003 Mar CFTG  
N77524 001 Apr 11, 2008 Mar NEWA

FLUOXETINE HYDROCHLORIDE

CAPSULE; ORAL

FLUOXETINE

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

FLUTICASON PROPIONATE

SPRAY, METERED; NASAL

FLUTICASON PROPIONATE

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

CAPSULE, EXTENDED RELEASE; ORAL

LUVOX CR

SOLVAY

+

		100MG	N22033 001	Feb 28, 2008	Feb	NEWA
		150MG	N22033 002	Feb 28, 2008	Feb	NEWA

FOMEPIZOLE

INJECTABLE; INJECTION

FOMEPIZOLE

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 DIMEGLUMINE

POWDER; INTRAVENOUS

EMEND

+

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

INJECTABLE; INJECTION

FOSPHENYTOIN SODIUM

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

GABAPENTIN

CAPSULE; ORAL

GABAPENTIN

	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
>D>	AB	MUTUAL PHARM	100MG	N76537 001	Jun 30, 2005	Mar	DISC
>A>		@	100MG	N76537 001	Jun 30, 2005	Mar	DISC
>D>	AB		300MG	N76537 002	Jun 30, 2005	Mar	DISC
>A>		@	300MG	N76537 002	Jun 30, 2005	Mar	DISC
>D>	AB		400MG	N76537 003	Jun 30, 2005	Mar	DISC
>A>		@	400MG	N76537 003	Jun 30, 2005	Mar	DISC

GLIPIZIDE; METFORMIN HYDROCHLORIDE

TABLET; ORAL

GLIPIZIDE AND METFORMIN HYDROCHLORIDE

AB	CARACO	2.5MG;250MG	N77620 001	Jan 11, 2008	Jan	NEWA
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## TABLET; ORAL

## GLIPIZIDE AND METFORMIN HYDROCHLORIDE

AB	CARACO	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

>D>	@ NUTRITIONAL RESTART	5GM/PACKET	N21667 001	Jun 10, 2004	Mar	CMFD
>A>	+	5GM/PACKET	N21667 001	Jun 10, 2004	Mar	CMFD

GLYCOPYRROLATE

## TABLET; ORAL

## GLYCOPYRROLATE

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

GRANISETRON HYDROCHLORIDE

## INJECTABLE; INJECTION

## GRANISETRON HYDROCHLORIDE

AP	WOCKHARDT USA	EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML)	N78566 001	Feb 29, 2008	Feb	NEWA
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## SOLUTION; ORAL

## GRANISETRON HYDROCHLORIDE

AA	CYPRESS PHARM	EQ 2MG BASE/10ML	N78334 001	Feb 28, 2008	Feb	NEWA
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## KYTRIL

AA	+	ROCHE	EQ 2MG BASE/10ML	N21238 001	Jun 27, 2001	Feb	CFTG
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## TABLET; ORAL

## GRANISETRON HYDROCHLORIDE

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

GRISEOFULVIN, MICROCRYSTALLINE

## SUSPENSION; ORAL

## GRIFULVIN V

AB	+	ORTHONEUTROGENA	125MG/5ML	N62483 001	Jan 26, 1984	Feb	CAHN
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## TABLET; ORAL

## FULVICIN-U/F

>D>	AB	+	SCHERING	250MG	N60569 002	Mar	DISC
>A>		@		250MG	N60569 002	Mar	DISC
>D>	AB	+		500MG	N60569 001	Mar	DISC
>A>		@		500MG	N60569 001	Mar	DISC

## GRIFULVIN V

## ORTHONEUTROGENA

>D>	AB			125MG	N62279 001	Feb	CAHN
>D>	AB			250MG	N62279 002	Mar	CRLD
>A>		+		250MG	N62279 002	Mar	CRLD
	AB			250MG	N62279 002	Feb	CAHN
>D>	AB			500MG	N62279 003	Mar	CRLD
>A>		+		500MG	N62279 003	Mar	CRLD
	AB			500MG	N62279 003	Feb	CAHN

GUANFACINE HYDROCHLORIDE

TABLET; ORAL

GUANFACINE HYDROCHLORIDE

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

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN SODIUM PRESERVATIVE FREE

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

SYRUP; ORAL

HYDROCODONE BITARTRATE AND HOMATROPINE METHYLBROMIDE

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

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

HYDRALAZINE HYDROCHLORIDE

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

HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

HYDROCHLOROTHIAZIDE

AB	CADISTA PHARMS	12.5MG	N78391 001	Feb 11, 2008	Jan	NEWA
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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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>D> HYDROXYZINE

&gt;D&gt; TABLET; ORAL

&gt;D&gt; HYDROXYZINE HYDROCHLORIDE

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

>A> HYDROXYZINE HYDROCHLORIDE

&gt;A&gt; TABLET; ORAL

&gt;A&gt; HYDROXYZINE HYDROCHLORIDE

>A>	AB	INVAGEN PHARMS	10MG	N40812 001	Mar 12, 2008	Mar	CAIN
>A>	AB		25MG	N40812 002	Mar 12, 2008	Mar	CAIN



>A> TABLET; ORAL  
 >A> HYDROXYZINE HYDROCHLORIDE  
 >A> AB INVAGEN PHARMS 50MG N40812 003 Mar 12, 2008 Mar CAIN  
 >A> AB NORTHSTAR HLTHCARE 10MG N40841 001 Mar 31, 2008 Mar NEWA  
 >A> AB 25MG N40842 001 Mar 31, 2008 Mar NEWA  
 >A> AB 50MG N40840 001 Mar 31, 2008 Mar NEWA

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL  
 IMIPRAMINE HYDROCHLORIDE  
 AB ACTAVIS TOTOWA 10MG N40753 001 Feb 28, 2008 Feb NEWA  
 AB 25MG N40752 001 Feb 28, 2008 Feb NEWA  
 AB 50MG N40751 001 Feb 28, 2008 Feb NEWA

IMIPRAMINE PAMOATE

CAPSULE; ORAL  
 TOFRANIL-PM  
 + TYCO HLTHCARE EQ 75MG HCL N17090 001 Jan CRLD  
 EQ 150MG HCL N17090 002 Jan CRLD

INDAPAMIDE

TABLET; ORAL  
 INDAPAMIDE  
 >D> AB MYLAN 2.5MG N74461 001 Mar 27, 1996 Mar CRLD  
 >A> AB + 2.5MG N74461 001 Mar 27, 1996 Mar CRLD  
 LOZOL  
 >D> AB SANOFI AVENTIS US 1.25MG N18538 002 Apr 29, 1993 Mar DISC  
 >A> @ 1.25MG N18538 002 Apr 29, 1993 Mar DISC  
 >D> AB + 2.5MG N18538 001 Jul 06, 1983 Mar DISC  
 >A> @ 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  
 SUPPOSITORY; RECTAL  
 INDOCIN  
 @ IROKO PHARMS 50MG N17814 001 Aug 13, 1984 Feb CAHN

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

## INJECTABLE; INJECTION

## IRINOTECAN HYDROCHLORIDE

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
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

>D>	AA	MUTUAL PHARM	300MG	N83633 001		Mar	DISC
>A>		@	300MG	N83633 001		Mar	DISC

ISOSORBIDE DINITRATE

## TABLET; SUBLINGUAL

## ISOSORBIDE DINITRATE

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

## ISOSORBIDE DINITRATE

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

KETOROLAC TROMETHAMINE

## INJECTABLE; INJECTION

## KETOROLAC TROMETHAMINE

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

LEUPROLIDE ACETATE

## IMPLANT; IMPLANTATION

## VIADUR

	+	JOHNSON AND JOHNSON	EQ 65MG BASE	N21088 001	Mar 03, 2000	Feb	CAHN
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LEVALBUTEROL HYDROCHLORIDE

## SOLUTION; INHALATION

## LEVALBUTEROL HYDROCHLORIDE

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

>A> LEVOLEUCOVORIN CALCIUM

&gt;A&gt; POWDER; IV (INFUSION)

&gt;A&gt; LEVOLEUCOVORIN

&gt;A&gt; + SPECTRUM PHARMS EQ 50MG BASE/VIAL N20140 001 Mar 07, 2008 Mar NEWA

LEVONORDEFRIN; MEPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION

POLOCAINE W/ LEVONORDEFRIN

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

LEVOTHYROXINE SODIUM\*\*

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

TABLET; ORAL

LEVOXYL

AB1, + KING PHARMS 0.2MG N21301 011 May 25, 2001 Jan CRLD  
AB3

@ 0.3MG N21301 012 May 25, 2001 Jan DISC

UNITHROID

AB1, STEVENS J 0.137MG N21210 012 Feb 08, 2008 Feb NEWA  
AB2,  
AB3LITHIUM CARBONATE

CAPSULE; ORAL

ESKALITH

AB + NOVEN THERAP 300MG N16860 001 Jan CAHN

LITHIUM CARBONATE

&gt;D&gt; + ROXANE 600MG N17812 003 Jan 28, 1987 Mar CTEC

&gt;A&gt; AB + 600MG N17812 003 Jan 28, 1987 Mar CTEC

&gt;A&gt; AB WEST WARD 600MG N78763 001 Apr 15, 2008 Mar NEWA

TABLET, EXTENDED RELEASE; ORAL

LITHOBID

AB + NOVEN THERAP 300MG N18027 001 Jan CAHN

LOVASTATIN

TABLET; ORAL

LOVASTATIN

&gt;A&gt; AB LUPIN 10MG N78296 001 Mar 14, 2008 Mar NEWA

MELOXICAM

TABLET; ORAL

MELOXICAM

@ ROXANE 7.5MG N77925 001 Jul 19, 2006 Feb DISC

@ 15MG N77925 002 Jul 19, 2006 Feb DISC

MEPROBAMATE

TABLET; ORAL

MEPROBAMATE

AA INVAGEN PHARMS 200MG N40797 001 Feb 27, 2008 Feb NEWA

AA 400MG N40797 002 Feb 27, 2008 Feb NEWA

AA + WATSON LABS 400MG N83308 001 Feb CTEC

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, EXTENDED RELEASE; ORAL

METFORMIN HYDROCHLORIDE

>A>	AB	NEUROSCI INC	500MG	N78321	001	Apr 17, 2008	Mar	NEWA
>A>	AB		750MG	N78321	002	Apr 17, 2008	Mar	NEWA

METHSCOPOLAMINE BROMIDE

TABLET; ORAL

PAMINE

AA	+	NYCOMED US	2.5MG	N08848	001		Feb	CAHN
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PAMINE FORTE

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

>A>	AB	ALAVEN PHARM	EQ 5MG BASE	N17854	002	May 05, 1987	Mar	CAHN
>A>	AB	+	EQ 10MG BASE	N17854	001		Mar	CAHN
>D>	AB	SCHWARZ PHARMA	EQ 5MG BASE	N17854	002	May 05, 1987	Mar	CAHN
>D>	AB	+	EQ 10MG BASE	N17854	001		Mar	CAHN

TABLET, ORALLY DISINTEGRATING; ORAL

REGLAN ODT

>A>		@ ALAVEN PHARM	EQ 5MG BASE	N21793	001	Jun 10, 2005	Mar	CAHN
>A>		@	EQ 10MG BASE	N21793	002	Jun 10, 2005	Mar	CAHN
>D>		@ SCHWARZ PHARMA	EQ 5MG BASE	N21793	001	Jun 10, 2005	Mar	CAHN
>D>		@	EQ 10MG BASE	N21793	002	Jun 10, 2005	Mar	CAHN

METOPROLOL SUCCINATE

TABLET, EXTENDED RELEASE; ORAL

METOPROLOL SUCCINATE

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

METRONIDAZOLE

INJECTABLE; INJECTION

METRONIDAZOLE IN PLASTIC CONTAINER

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

CREAM; TOPICAL

MONISTAT-DERM

	+	ORTHONEUTROGENA	2%	N17494	001		Feb	CAHN
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MINOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL

MINOCYCLINE HYDROCHLORIDE

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

TABLET; ORAL

MINOCYCLINE HYDROCHLORIDE

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

MINOXIDIL

TABLET; ORAL

LONITEN

@ PHARMACIA AND UPJOHN 2.5MG

N18154 001

Jan DISC

@ 10MG

N18154 003

Jan DISC

MINOXIDIL

>D>	AB	WATSON LABS	10MG	N71345 001	Mar 03, 1987	Mar	CRLD
>A>	AB	+	10MG	N71345 001	Mar 03, 1987	Mar	CRLD

MOMETASONE FUROATE

POWDER; INHALATION

ASMANEX TWISTHALER

SCHERING 0.11MG/INH

N21067 002

Feb 01, 2008

Feb

NEWA

MORPHINE SULFATE

&gt;A&gt; SOLUTION; ORAL

&gt;A&gt; MORPHINE SULFATE

&gt;A&gt; ROXANE 10MG/5ML

N22195 001

Mar 17, 2008

Mar

NEWA

>A> + 20MG/5ML

N22195 002

Mar 17, 2008

Mar

NEWA

>A> TABLET; ORAL

>A> MORPHINE SULFATE

>A> ROXANE 15MG

N22207 001

Mar 17, 2008

Mar

NEWA

>A> + 30MG

N22207 002

Mar 17, 2008

Mar

NEWA

MUPIROCIN

OINTMENT; TOPICAL

CENTANY

BX ORTHONEUTROGENA 2%

N50788 001

Dec 04, 2002

Feb

CAHN

NABUMETONE

TABLET; ORAL

NABUMETONE

AB INVAGEN PHARMS 500MG

N78671 001

Mar 07, 2008

Feb

NEWA

AB 750MG

N78671 002

Mar 07, 2008

Feb

NEWA

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

NICARDIPINE HYDROCHLORIDE

AB	AMNEAL PHARM	20MG	N74928 001	Mar 19, 1998	Feb	CAHN
AB		30MG	N74928 002	Mar 19, 1998	Feb	CAHN

NIMODIPINE

CAPSULE; ORAL

NIMODIPINE

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

TABLET, EXTENDED RELEASE; ORAL

SULAR

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

NITROFURAZONE

OINTMENT; TOPICAL

NITROFURAZONE

@	TARO	0.2%	N86156 001		Jan	DISC
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NYSTATIN

TABLET; ORAL

NYSTATIN

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

INJECTABLE; INJECTION

OCTREOTIDE ACETATE

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

OFLOXACIN

SOLUTION/DROPS; OPHTHALMIC

OFLOXACIN

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

OFLOXACIN

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

OMEPRAZOLE MAGNESIUM

&gt;A&gt; FOR SUSPENSION, DELAYED RELEASE; ORAL

&gt;A&gt; PRILOSEC

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

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION

ONDANSETRON HYDROCHLORIDE AND DEXTROSE IN PLASTIC CONTAINER

>A>	AP	CLARIS LIFESCIENCES	EQ 0.64MG BASE/ML	N78308 001	Mar 17, 2008	Mar	NEWA
ONDANSETRON HYDROCHLORIDE PRESERVATIVE FREE							
>A>	AP	TARO PHARMS IRELAND	EQ 2MG BASE/ML	N78014 001	Mar 21, 2008	Mar	NEWA

OXCARBAZEPINE

TABLET; ORAL

OXCARBAZEPINE

>A>	AB	APOTEX INC	150MG	N77747 001	Apr 09, 2008	Mar	NEWA
>A>	AB		300MG	N77747 002	Apr 09, 2008	Mar	NEWA
>A>	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

&gt;D&gt; CAPSULE; ORAL

&gt;D&gt; TERRAMYCIN

>D>	+	PFIZER	EQ 250MG BASE	N50286 002		Mar	DISC
>A>	@		EQ 250MG BASE	N50286 002		Mar	DISC

OXYTOCIN

INJECTABLE; INJECTION

OXYTOCIN

AP	+	APP PHARMS	100USP UNITS/10 ML (10USP UNITS/ML)	N18248 002		Jan	CFTG
>A>	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

## INJECTABLE; INJECTION

## OXYTOCIN

AP	TEVA PARENTERAL	100USP UNITS/10ML (10USP UNITS/ML)	N77453 002	Jan 24, 2008	Jan	NEWA
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>D> INJECTABLE; INTRAMUSCULAR, IV (INFUSION)

>D> OXYTOCIN

>D> AP	+ BAXTER HLTHCARE CORP	100USP UNITS/10ML (10USP UNITS/ML)	N18243 002	Jan 10, 2007	Mar	CDFR
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AP	+	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
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		9MG	N21999 003	Dec 19, 2006	Jan	CRLD
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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
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+		EQ 0.25MG BASE/5ML (EQ 0.05MG BASE/ML)	N21372 001	Jul 25, 2003	Feb	CPOT
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PAROXETINE HYDROCHLORIDE

## TABLET; ORAL

## PAROXETINE HYDROCHLORIDE

>A> AB	MYLAN	EQ 10MG BASE	N78902 001	Mar 13, 2008	Mar	NEWA
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>A> AB		EQ 20MG BASE	N78902 002	Mar 13, 2008	Mar	NEWA
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>A> AB		EQ 30MG BASE	N78902 003	Mar 13, 2008	Mar	NEWA
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>A> AB		EQ 40MG BASE	N78902 004	Mar 13, 2008	Mar	NEWA
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PHENDIMETRAZINE TARTRATE

## TABLET; ORAL

## PHENDIMETRAZINE TARTRATE

>A> AA	ACTAVIS TOTOWA	35MG	N40762 001	Jan 28, 2008	Mar	CAHN
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>D> AA	AMIDE PHARM	35MG	N40762 001	Jan 28, 2008	Mar	CAHN
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AA		35MG	N40762 001	Jan 28, 2008	Jan	NEWA
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PHENTERMINE HYDROCHLORIDE

## CAPSULE; ORAL

## PHENTERMINE HYDROCHLORIDE

>A> AA	KVK TECH	15MG	N40886 002	Mar 31, 2008	Mar	NEWA
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>A> AA		30MG	N40875 001	Mar 21, 2008	Mar	NEWA
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>A> AA		30MG	N40886 001	Mar 31, 2008	Mar	NEWA
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## TABLET; ORAL

## PHENTERMINE HYDROCHLORIDE

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

CAPSULE; ORAL

EXTENDED PHENYTOIN SODIUM

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

PHENYTOIN SODIUM

>A>	AP	+	BAXTER	50MG/ML	N84307 001		Mar	CAHN
>D>	AP	+	ELKINS SINN	50MG/ML	N84307 001		Mar	CAHN

POTASSIUM CHLORIDE

TABLET, EXTENDED RELEASE; ORAL

POTASSIUM CHLORIDE

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

PRAMIPEXOLE DIHYDROCHLORIDE

TABLET; ORAL

MIRAPEX

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

PREDNISOLONE ACETATE

SUSPENSION; ORAL

FLO-PRED

TARO

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

SOLUTION; ORAL

PREDNISOLONE SODIUM PHOSPHATE

AA		PHARM ASSOC	EQ 10MG BASE/5ML	N78465 001	Mar 07, 2008	Feb	NEWA
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PRIMIDONE

TABLET; ORAL

PRIMIDONE

AB		IMPAX LABS	50MG	N40717 001	Feb 12, 2008	Jan	NEWA
AB			250MG	N40717 002	Feb 12, 2008	Jan	NEWA

PROCHLORPERAZINE EDISYLATE

INJECTABLE; INJECTION

PROCHLORPERAZINE EDISYLATE

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

TABLET; ORAL

PHENERGAN

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

AB	ACTAVIS TOTOWA	12.5MG	N40673 001	Mar 05, 2008	Feb	NEWA
AB		25MG	N40673 002	Mar 05, 2008	Feb	NEWA
AB		50MG	N40673 003	Mar 05, 2008	Feb	NEWA
AB	IMPAX LABS	12.5MG	N40724 001	Feb 12, 2008	Jan	NEWA
AB		25MG	N40724 002	Feb 12, 2008	Jan	NEWA

PROPRANOLOL HYDROCHLORIDE

INJECTABLE; INJECTION

PROPRANOLOL HYDROCHLORIDE

AP	HIKMA FARMACEUTICA	1MG/ML	N77760 001	Jan 31, 2008	Jan	NEWA
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QUETIAPINE FUMARATE

TABLET, EXTENDED RELEASE; ORAL

SEROQUEL XR

>D>	ASTRAZENECA	EQ 200MG BASE	N22047 002	May 17, 2007	Mar	CRLD
>A>	+	EQ 200MG BASE	N22047 002	May 17, 2007	Mar	CRLD
>D>	+	EQ 400MG BASE	N22047 004	May 17, 2007	Mar	CRLD
>A>		EQ 400MG BASE	N22047 004	May 17, 2007	Mar	CRLD

RIFAMPIN

CAPSULE; ORAL

RIFAMPIN

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

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

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

INJECTABLE; INJECTION

ACCRETROPIN

+ CANGENE	5MG/ML (5MG/ML)	N21538 001	Jan 23, 2008	Jan	NEWA
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NORDITROPIN

BX NOVO NORDISK INC	5MG/1.5ML	N21148 001	Jun 20, 2000	Jan	CTEC
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NORDITROPIN NORDIFLEX

BX NOVO NORDISK INC	5MG/1.5ML	N21148 004	Oct 01, 2004	Jan	CTEC
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NUTROPIN AQ

+ GENENTECH	5MG/2ML (2.5MG/ML)	N20522 003	Jan 03, 2008	Jan	NEWA
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+ GENENTECH	10MG/2ML (5MG/ML)	N20522 001	Dec 29, 1995	Jan	CPOT
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+ GENENTECH	20MG/2ML (10MG/ML)	N20522 004	Jan 03, 2008	Jan	NEWA
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NUTROPIN AQ PEN

+ GENENTECH	10MG/2ML (5MG/ML)	N20522 002	Apr 22, 2002	Jan	CPOT
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OMNITROPE

BX SANDOZ	5MG/1.5ML	N21426 003	Jan 16, 2008	Jan	NEWA
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TEV-TROPIN

BX + FERRING	5MG/VIAL	N19774 002	Jan 04, 2002	Jan	CPOT
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INJECTABLE; SUBCUTANEOUS

SEROSTIM LQ

+ EMD SERONO	6MG/0.5ML (6MG/0.5ML)	N20604 005	Feb 11, 2005	Feb	CMFD
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SOTALOL HYDROCHLORIDE

TABLET; ORAL

SOTALOL HYDROCHLORIDE

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

TABLET; ORAL

SPIRONOLACTONE

>D> AB MUTUAL PHARM	25MG	N87265 001		Mar	DISC
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>A> @	25MG	N87265 001		Mar	DISC
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SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION

SULFAMETHOXAZOLE AND TRIMETHOPRIM

>D> AP BAXTER HLTHCARE	80MG/ML;16MG/ML	N70628 001	Dec 29, 1987	Mar	DISC
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>A> @	80MG/ML;16MG/ML	N70628 001	Dec 29, 1987	Mar	DISC
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INJECTABLE; INJECTIONSULFAMETHOXAZOLE AND TRIMETHOPRIM

>D>	AP	HOSPIRA	80MG/ML;16MG/ML	N73199 001	Sep 11, 1992	Mar	DISC
>A>		@	80MG/ML;16MG/ML	N73199 001	Sep 11, 1992	Mar	DISC
>D>	AP	TEVA PARENTERAL	80MG/ML;16MG/ML	N73303 001	Oct 31, 1991	Mar	CRLD
>A>		+	80MG/ML;16MG/ML	N73303 001	Oct 31, 1991	Mar	CRLD

SULFASALAZINE

## TABLET; ORAL

SULFASALAZINE

>D>	AB	MUTUAL PHARM	500MG	N89590 001	Oct 19, 1987	Mar	DISC
>A>		@	500MG	N89590 001	Oct 19, 1987	Mar	DISC

TADALAFIL

## TABLET; ORAL

CIALIS

## LILLY

2.5MG

N21368 004 Jan 07, 2008 Jan NEWA

TECHNETIUM TC-99M MEBROFENIN KITINJECTABLE; INJECTIONCHOLETEC

AP	+	BRACCO	N/A	N18963 001	Jan 21, 1987	Jan	CFTG
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TECHNETIUM TC-99M MEBROFENIN

AP		CIS	N/A	N78242 001	Jan 29, 2008	Jan	NEWA
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TECHNETIUM TC-99M MEDRONATE KITINJECTABLE; INJECTIONDRAXIMAGE MDP-25

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

TERAZOSIN HYDROCHLORIDE

## CAPSULE; ORAL

TERAZOSIN HYDROCHLORIDE

@	MYLAN TECHNOLOGIES	EQ 1MG BASE	N75384 001	Dec 01, 2000	Feb	DISC
@		EQ 2MG BASE	N75384 002	Dec 01, 2000	Feb	DISC
@		EQ 5MG BASE	N75384 003	Dec 01, 2000	Feb	DISC
@		EQ 10MG BASE	N75384 004	Dec 01, 2000	Feb	DISC

TESTOLACTONE

## TABLET; ORAL

TESLAC

@ BRISTOL MYERS SQUIBB 50MG

N16118 001 Feb DISC

THEOPHYLLINE

## TABLET, EXTENDED RELEASE; ORAL

UNIPHYL

AB		PURDUE PHARM PRODS	400MG	N87571 001	Sep 01, 1982	Feb	CAHN
AB	+		600MG	N40086 001	Apr 15, 1996	Feb	CAHN

THIORIDAZINE HYDROCHLORIDE

## TABLET; ORAL

THIORIDAZINE HYDROCHLORIDE

@ MUTUAL PHARM 50MG

N88370 001 Nov 18, 1983 Feb DISC

TIROFIBAN HYDROCHLORIDE

INJECTABLE; INJECTION

AGGRASTAT

>D>	+	MEDICURE	EQ 12.5MG BASE/50ML (EQ 0.25MG BASE/ML)	N20912 001	May 14, 1998	Mar	DISC
>A>	@		EQ 12.5MG BASE/50ML (EQ 0.25MG BASE/ML)	N20912 001	May 14, 1998	Mar	DISC

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION

TOBRAMYCIN

>D>							
>D>	AP	ABRAXIS PHARM	EQ 10MG BASE/ML	N65122 001	Nov 29, 2002	Mar	CTNA
>D>	AP	+	EQ 40MG BASE/ML	N65122 002	Nov 29, 2002	Mar	CTNA
>D>	AP	APP PHARMS	EQ 1.2GM BASE/VIAL	N50789 001	Jul 13, 2004	Mar	CTNA
	AP		EQ 1.2GM BASE/VIAL	N50789 001	Jul 13, 2004	Feb	CTEC
>D>	AP	X GEN PHARMS	EQ 1.2GM BASE/VIAL	N65013 001	Aug 17, 2001	Mar	CTNA
	AP	+	EQ 1.2GM BASE/VIAL	N65013 001	Aug 17, 2001	Feb	CTEC
>D>		TOBRAMYCIN (PHARMACY BULK)					
>D>	AP	ABRAXIS PHARM	EQ 40MG BASE/ML	N65120 001	Nov 29, 2002	Mar	CTNA
>A>		TOBRAMYCIN SULFATE					
>A>	AP	ABRAXIS PHARM	EQ 10MG BASE/ML	N65122 001	Nov 29, 2002	Mar	CTNA
>A>	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
>A>	AP	APP PHARMS	EQ 1.2GM BASE/VIAL	N50789 001	Jul 13, 2004	Mar	CTNA
>A>	AP	X GEN PHARMS	EQ 1.2GM BASE/VIAL	N65013 001	Aug 17, 2001	Mar	CTNA
>A>		TOBRAMYCIN SULFATE (PHARMACY BULK)					
>A>	AP	ABRAXIS PHARM	EQ 40MG BASE/ML	N65120 001	Nov 29, 2002	Mar	CTNA

TORSEMIDE

TABLET; ORAL

TORSEMIDE

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

VALPROIC ACID

SYRUP; ORAL

VALPROIC ACID

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

TABLET; ORAL

LEVITRA

BAYER HLTHCARE

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

VINORELBINE TARTRATE

INJECTABLE; INJECTION

VINORELBINE TARTRATE

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

TABLET; ORAL

ZIDOVUDINE

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

OTC DRUG PRODUCT LIST - 28TH EDITION

OTC DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2008

2-1

>A>	<u>AVOBENZONE; ECAMSULE; OCTOCRYLENE; TITANIUM DIOXIDE</u>				
>A>	CREAM; TOPICAL				
>A>	ANTHELIOS 40				
>A>	+ LOREAL USA	2%;3%;10%;5%	N22009 001	Mar 31, 2008	Mar NEWA
	<u>CALCIUM CARBONATE; FAMOTIDINE; MAGNESIUM HYDROXIDE</u>				
	TABLET, CHEWABLE; ORAL				
	CALCIUM CARBONATE, FAMOTIDINE AND MAGNESIUM HYDROXIDE				
	PERRIGO R AND D	800MG;10MG;165MG	N77355 001	Feb 06, 2008	Jan NEWA
	<u>CETIRIZINE HYDROCHLORIDE</u>				
	SYRUP; ORAL				
>A>	CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY				
>A>	PERRIGO R AND D	5MG/ML	N90254 002	Apr 09, 2008	Mar NEWA
>A>	CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF				
>A>	PERRIGO R AND D	5MG/ML	N90254 001	Apr 09, 2008	Mar NEWA
	CHILDREN'S ZYRTEC ALLERGY				
>D>	+ MCNEIL CONSUMER	1MG/ML	N22155 002	Nov 16, 2007	Mar CPOT
>A>		5MG/5ML	N22155 002	Nov 16, 2007	Mar CPOT
		1MG/ML	N22155 002	Nov 16, 2007	Jan CAHN
	CHILDREN'S ZYRTEC HIVES RELIEF				
>D>	+ MCNEIL CONSUMER	1MG/ML	N22155 001	Nov 16, 2007	Mar CPOT
>A>		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				
	DR REDDYS LABS LTD	5MG	N78343 004	Jan 15, 2008	Jan NEWA
		10MG	N78343 003	Jan 15, 2008	Jan NEWA
	CETIRIZINE HYDROCHLORIDE HIVES				
	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
	<u>CETIRIZINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE</u>				
	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

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)

>A>	HI TECH PHARMA	2%	N74731	002	May 11, 2005	Mar	NEWA
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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 03 MARCH 2008**

NO MARCH 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 MARCH 2008 ADDITIONS

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 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>ACARBOSE - PRECOSE</u>						
020482 001	>A> 4904769	Sep 06, 2009		Y		
<u>ACARBOSE - PRECOSE</u>						
020482 002	>A> 4904769	Sep 06, 2009		Y		
<u>ACARBOSE - PRECOSE</u>						
020482 004	>A> 4904769	Sep 06, 2009		Y		
<u>ADEFOVIR DIPIVOXIL - HEPSERA</u>						
021449 001					NPP	Dec 19, 2010
<u>ALENDRONATE SODIUM - ALENDRONATE SODIUM</u>						
075710 001					>A> PC	Aug 04, 2008
<u>ALENDRONATE SODIUM - ALENDRONATE SODIUM</u>						
075710 002					>A> PC	Aug 04, 2008
<u>ALENDRONATE SODIUM - ALENDRONATE SODIUM</u>						
075710 003					PC	Aug 04, 2008
<u>ALENDRONATE SODIUM - ALENDRONATE SODIUM</u>						
075710 004					>A> PC	Aug 04, 2008
<u>ALENDRONATE SODIUM - ALENDRONATE SODIUM</u>						
075710 005					>A> PC	Aug 04, 2008
<u>ALENDRONATE SODIUM - ALENDRONATE SODIUM</u>						
076184 001					PC	Aug 04, 2008
<u>ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE - TEKTURNA HCT</u>						
022107 001					NCE NC	Mar 05, 2012 Jan 18, 2011
<u>ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE - TEKTURNA HCT</u>						
022107 002					NCE NC	Mar 05, 2012 Jan 18, 2011
<u>ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE - TEKTURNA HCT</u>						
022107 003					NCE NC	Mar 05, 2012 Jan 18, 2011
<u>ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE - TEKTURNA HCT</u>						
022107 004					NCE NC	Mar 05, 2012 Jan 18, 2011
<u>ALOSETRON HYDROCHLORIDE - LOTRONEX</u>						
021107 001					>A> D-113	Apr 01, 2011
<u>ALOSETRON HYDROCHLORIDE - LOTRONEX</u>						
021107 002					>A> D-113	Apr 01, 2011
<u>APREPITANT - EMEND</u>						
021549 001	5719147	Apr 17, 2015	DS DP U-853			
	7214692	Sep 18, 2012				
<u>APREPITANT - EMEND</u>						
021549 002	7214692	Sep 18, 2012				
<u>APREPITANT - EMEND</u>						
021549 003	7214692	Sep 18, 2012				

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2008

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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>ARIPIPIRAZOLE - ABILIFY</u>						
021436 001					D-110 I-555 PED PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPIRAZOLE - ABILIFY</u>						
021436 002					D-110 I-555 PED PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPIRAZOLE - ABILIFY</u>						
021436 003					D-110 I-555 PED PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPIRAZOLE - ABILIFY</u>						
021436 004					D-110 I-555 PED PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPIRAZOLE - ABILIFY</u>						
021436 005					D-110 I-555 PED PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPIRAZOLE - ABILIFY</u>						
021436 006					D-110 I-555 PED PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPIRAZOLE - ABILIFY</u>						
021713 001					D-110 I-555 PED PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPIRAZOLE - ABILIFY</u>						
021729 002					D-110 I-555 PED PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPIRAZOLE - ABILIFY</u>						
021729 003					D-110 I-555 PED PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPIRAZOLE - ABILIFY</u>						
021729 004					D-110 I-555 PED PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2008

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>ARIPIPIRAZOLE - ABILIFY</u>						
021729	005				D-110 I-555 PED PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPIRAZOLE - ABILIFY</u>						
021866	001				D-110 I-555 PED PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ATAZANAVIR SULFATE - REYATAZ</u>						
021567	001				>A> NPP	Mar 25, 2011
<u>ATAZANAVIR SULFATE - REYATAZ</u>						
021567	002				>A> NPP	Mar 25, 2011
<u>ATAZANAVIR SULFATE - REYATAZ</u>						
021567	003				>A> NPP	Mar 25, 2011
<u>ATAZANAVIR SULFATE - REYATAZ</u>						
021567	004				>A> NPP	Mar 25, 2011
<u>AVOBENZONE; ECAMSULE; OCTOCRYLENE; TITANIUM DIOXIDE - ANTHELIOS 40</u>						
022009	001				>A> NP >A> NC	Mar 31, 2011 Oct 05, 2009
<u>BENDAMUSTINE HYDROCHLORIDE - TREANDA</u>						
022249	001				>A> NCE >A> ODE	Mar 20, 2013 Mar 20, 2015
<u>BETAMETHASONE DIPROPIONATE; CALCIPOTRIENE HYDRATE - TACLONEX</u>						
021852	001	>A> RE39706	Jun 09, 2015	DS DP		
<u>BRIMONIDINE TARTRATE; TIMOLOL MALEATE - COMBIGAN</u>						
021398	001	7030149	Apr 19, 2022		U-849	
		>A> 7320976	Apr 19, 2022		U-849	
		7323463	Jan 19, 2023		DP	
<u>BUDESONIDE - RHINOCORT</u>						
020746	001	>A> 6291445	Apr 29, 2017			Y
		>A> 6686346	Apr 29, 2017	DP U-557		Y
		>A> 6986904	Apr 29, 2017	DP U-699		Y
<u>BUPROPION HYDROCHLORIDE - WELLBUTRIN XL</u>						
021515	001	>A> 6143327	Oct 30, 2018			Y
<u>CALCIPOTRIENE - DOVONEX</u>						
020554	001	>A> RE39706	Jun 09, 2015	DS DP		
<u>CALCIPOTRIENE - DOVONEX</u>						
020611	001	>A> RE39706	Jun 09, 2015	DS DP		
<u>CARVEDILOL - COREG</u>						
020297	001	RE40000	Jun 07, 2015		U-233	
		RE40000*PED	Dec 07, 2015			
<u>CARVEDILOL - COREG</u>						
020297	002	RE40000	Jun 07, 2015		U-233	
		RE40000*PED	Dec 07, 2015			

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 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 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	>A> 5378804	Mar 16, 2013	DS			
	>A> 5378804*PED	Sep 16, 2013				
	>A> 5514650	Jan 26, 2015	DP U-607			
	>A> 5514650*PED	Jul 26, 2015				
	>A> 5792746	Mar 16, 2013	DS DP U-607			
	>A> 5792746*PED	Sep 16, 2013				
	>A> 5952300	Mar 28, 2017	DP			
	>A> 5952300*PED	Sep 28, 2017				
	>A> 6136783	Mar 28, 2017	U-607			
	>A> 6136783*PED	Sep 28, 2017				
<u>CASPOFUNGIN ACETATE - CANCIDAS</u>						
021227 002	>A> 5378804	Mar 16, 2013	DS			
	>A> 5378804*PED	Sep 16, 2013				
	>A> 5514650	Jan 26, 2015	DP U-607			
	>A> 5514650*PED	Jul 26, 2015				
	>A> 5792746	Mar 16, 2013	DS DP U-607			
	>A> 5792746*PED	Sep 16, 2013				
	>A> 5952300	Mar 28, 2017	DP			
	>A> 5952300*PED	Sep 28, 2017				
	>A> 6136783	Mar 28, 2017	U-607			
	>A> 6136783*PED	Sep 28, 2017				

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2008

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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					>A> PC	Sep 16, 2008
<u>CLOFARABINE - CLOLAR</u>						
021673 001	5661136	Jan 14, 2018	U-626			
<u>CLOPIDOGREL BISULFATE - PLAVIX</u>						
020839 001	>A> 5576328	Jan 31, 2014	U-432	Y		



## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2008

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<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>DAPTOMYCIN - CUBICIN</u>						
021572 002	RE39071	Jun 15, 2016	DS DP	U-728		
<u>DARIFENACIN HYDROBROMIDE - ENABLEX</u>						
021513 001	5096890	Mar 13, 2015	DS DP	U-631		
<u>DARIFENACIN HYDROBROMIDE - ENABLEX</u>						
021513 002	5096890	Mar 13, 2015	DS DP	U-631		
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
021976 002					NCE	Jun 23, 2011
<u>DESVENLAFAXINE SUCCINATE - PRISTIQ</u>						
021992 001	>A> 6673838	Feb 11, 2022	DS DP	U-860	>A> NCE	Mar 01, 2013
	>A> 7291347	Feb 11, 2022	DP			
<u>DESVENLAFAXINE SUCCINATE - PRISTIQ</u>						
021992 002	>A> 6673838	Feb 11, 2022	DS DP	U-860	>A> NCE	Mar 01, 2013
	>A> 7291347	Feb 11, 2022	DP			
<u>DEXTROAMPHETAMINE SULFATE - DEXTROAMPHETAMINE SULFATE</u>						
076814 001					PC	Aug 04, 2008
<u>DIVALPROEX SODIUM - DEPAKOTE</u>						
019680 001					>A> M-34 >A> PED	Mar 24, 2011 Sep 24, 2011
<u>DIVALPROEX SODIUM - DEPAKOTE ER</u>						
021168 001					>A> M-34 >A> PED	Mar 24, 2011 Sep 24, 2011
<u>DIVALPROEX SODIUM - DEPAKOTE ER</u>						
021168 002					>A> M-34 >A> PED	Mar 24, 2011 Sep 24, 2011
<u>DONEPEZIL HYDROCHLORIDE - ARICEPT</u>						
020690 001	>A> 6372760	Mar 31, 2019			Y	
<u>DONEPEZIL HYDROCHLORIDE - ARICEPT</u>						
020690 002	>A> 6372760	Mar 31, 2019			Y	
<u>DORZOLAMIDE HYDROCHLORIDE; TIMOLOL MALEATE - COSOPT</u>						
020869 001	>A> 6248735	Apr 17, 2011			Y	
	>A> 6316443	Apr 17, 2011	DP	U-561	Y	
<u>ELETRIPTAN HYDROBROMIDE - RELPAX</u>						
021016 001	6110940	Aug 29, 2017				
<u>ELETRIPTAN HYDROBROMIDE - RELPAX</u>						
021016 002	6110940	Aug 29, 2017				
<u>ENFUVIRTIDE - FUZEON</u>						
021481 001	>A> 6133418	Nov 17, 2015	DS DP			

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 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>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>ESCITALOPRAM OXALATE - LEXAPRO</u>						
021323 001	>A> 6916941	Aug 12, 2022	DS DP			
	>A> 6916941*PED	Feb 12, 2023	DS DP			
<u>ESCITALOPRAM OXALATE - LEXAPRO</u>						
021323 002	>A> 6916941	Aug 12, 2022	DS DP			
	>A> 6916941*PED	Feb 12, 2023	DS DP			
<u>ESCITALOPRAM OXALATE - LEXAPRO</u>						
021323 003	>A> 6916941	Aug 12, 2022	DS DP			
	>A> 6916941*PED	Feb 12, 2023	DS DP			
<u>ESOMEPRAZOLE MAGNESIUM - NEXIUM</u>						
022101 001	>A> 5690960	Nov 25, 2014	DP U-858		>A> I-504	Oct 11, 2009
	>A> 5690960*PED	May 25, 2015			>A> NPP	Feb 27, 2011
	>A> 5714504	Feb 03, 2015	DP U-858			
	>A> 5714504*PED	Aug 03, 2015				
	>A> 5877192	May 27, 2014	U-858			
	>A> 5877192*PED	Nov 27, 2014				
	>A> 5900424	May 04, 2016	DS U-858			
	>A> 5900424*PED	Nov 04, 2016				
	>A> 6369085	May 25, 2018	DS DP U-858			
	>A> 6369085*PED	Nov 25, 2018				
	>A> 6428810	Nov 03, 2019	DP U-858			
	>A> 6428810*PED	May 03, 2020				
	>A> 6875872	May 27, 2014	DS			
	>A> 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			

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<u>EZETIMIBE - ZETIA</u>						
021445 001	5846966	Sep 21, 2013	U-474		I-493	May 23, 2009
	5846966*PED	Mar 21, 2014			PED	Nov 23, 2009
	7030106	Jan 25, 2022	DP			
	7030106*PED	Jul 25, 2022				
	RE37721	Oct 25, 2016	DS DP U-473			
	RE37721*PED	Apr 25, 2017				
<u>EZETIMIBE; SIMVASTATIN - VYTORIN</u>						
021687 001	5846966	Sep 21, 2013	DP U-593		>A> M-60	Oct 03, 2009
	5846966*PED	Mar 21, 2014			>A> M-58	Mar 16, 2009
	>A> 7229982	Dec 11, 2023	DP U-592		>A> PED	Apr 03, 2010
	>A> 7229982*PED	Jun 11, 2024			>A> PED	Sep 16, 2009
	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		>A> M-60	Oct 03, 2009
	5846966*PED	Mar 21, 2014			>A> M-58	Mar 16, 2009
	>A> 7229982	Dec 11, 2023	DP U-592		>A> PED	Apr 03, 2010
	>A> 7229982*PED	Jun 11, 2024			>A> PED	Sep 16, 2009
	RE37721	Oct 25, 2016	DS DP U-473			
	RE37721*PED	Apr 25, 2017				
<u>EZETIMIBE; SIMVASTATIN - VYTORIN</u>						
021687 003	5846966	Sep 21, 2013	DP U-593		>A> M-60	Oct 03, 2009
	5846966*PED	Mar 21, 2014			>A> M-58	Mar 16, 2009
	>A> 7229982	Dec 11, 2023	DP U-592		>A> PED	Apr 03, 2010
	>A> 7229982*PED	Jun 11, 2024			>A> 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		>A> M-60	Oct 03, 2009
	5846966*PED	Mar 21, 2014			>A> M-58	Mar 16, 2009
	>A> 7229982	Dec 11, 2023	DP U-592		>A> PED	Apr 03, 2010
	>A> 7229982*PED	Jun 11, 2024			>A> PED	Sep 16, 2009
	RE37721	Oct 25, 2016	DS DP U-473			
	RE37721*PED	Apr 25, 2017				
<u>FAMOTIDINE - PEPCID AC</u>						
020801 001	>A> 5667794	May 02, 2015		Y		
<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>FLUOCINONIDE - VANOS</u>						
021758 001	>A> 7220424	Jan 07, 2023	U-861			

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<u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u>						
021520 002	>A> 5945416	Mar 24, 2017	DS DP	Y		
<u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u>						
021520 003	>A> 5945416	Mar 24, 2017	DS DP	Y		
<u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u>						
021520 004	>A> 5945416	Mar 24, 2017	DS DP	Y		
<u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u>						
021520 005	>A> 5945416	Mar 24, 2017	DS DP	Y		
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 100/50</u>						
021077 001	RE40045	Sep 07, 2010	DP			
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 250/50</u>						
021077 002	RE40045	Sep 07, 2010	DP			
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 500/50</u>						
021077 003	RE40045	Sep 07, 2010	DP			
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR HFA</u>						
021254 001	RE40045	Sep 07, 2010	DP			
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR HFA</u>						
021254 002	RE40045	Sep 07, 2010	DP			
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR HFA</u>						
021254 003	RE40045	Sep 07, 2010	DP			
<u>FLUVOXAMINE MALEATE - LUVOX CR</u>						
022033 001					NDF	Feb 28, 2011
<u>FLUVOXAMINE MALEATE - LUVOX CR</u>						
022033 002					NDF	Feb 28, 2011
<u>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	>A> 4916246	Apr 10, 2012	DS			
<u>GADOBENATE DIMEGLUMINE - MULTIHANCE</u>						
021357 002	>A> 4916246	Apr 10, 2012	DS			
<u>GADOBENATE DIMEGLUMINE - MULTIHANCE</u>						
021357 003	>A> 4916246	Apr 10, 2012	DS			
<u>GADOBENATE DIMEGLUMINE - MULTIHANCE</u>						
021357 004	>A> 4916246	Apr 10, 2012	DS			
<u>GADOBENATE DIMEGLUMINE - MULTIHANCE MULTIPACK</u>						
021358 001	>A> 4916246	Apr 10, 2012	DS			
<u>GADOBENATE DIMEGLUMINE - MULTIHANCE MULTIPACK</u>						
021358 002	>A> 4916246	Apr 10, 2012	DS			

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<u>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</u>						
021700 004	5002953	Sep 17, 2011	DS DP U-840			
<u>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</u>						
021700 005	5002953	Sep 17, 2011	DS DP U-840			
<u>GRANISETRON HYDROCHLORIDE - GRANISETRON HYDROCHLORIDE</u>						
077177 001					PC	Jun 28, 2008
<u>GRANISETRON HYDROCHLORIDE - GRANISETRON HYDROCHLORIDE PRESERVATIVE FREE</u>						
077165 001					PC	Jun 28, 2008
<u>HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM - HYZAAR</u>						
020387 001	>A> 5608075	Mar 04, 2014		Y		
<u>HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM - HYZAAR</u>						
020387 002	>A> 5608075	Mar 04, 2014		Y		
<u>INSULIN ASPART RECOMBINANT - NOVOLOG</u>						
020986 001					>A> 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	>A> 5422368	Mar 22, 2011	DP U-778	Y		
<u>LEVOCETIRIZINE DIHYDROCHLORIDE - XYZAL</u>						
022157 001	5698558	Sep 24, 2012	U-852		>A> NP	May 25, 2010
<u>LEVOLEUCOVORIN CALCIUM - LEVOLEUCOVORIN</u>						
020140 001	>A> 6500829	Dec 31, 2019	DS DP		>A> NP >A> ODE	Mar 07, 2011 Mar 07, 2015
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
021977 004	7105486	Jun 29, 2023	U-842			
	7223735	Jun 29, 2023	DP			
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
021977 005	7105486	Jun 29, 2023	U-842			
	7223735	Jun 29, 2023	DP			
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
021977 006	7105486	Jun 29, 2023	U-842			
	7223735	Jun 29, 2023	DP			
<u>LOPERAMIDE HYDROCHLORIDE; SIMETHICONE - IMODIUM ADVANCED</u>						
020606 001	>A> 5248505	Jul 28, 2010		Y		
	>A> 5612054	Sep 28, 2010		Y		
	>A> 5679376	Oct 21, 2014		Y		
	>A> 5716641	May 21, 2012	U-226	Y		
<u>LOPINAVIR; RITONAVIR - KALETRA</u>						
021226 001	>A> 5914332	Dec 13, 2015	U-351			
	>A> 5914332*PED	Jun 13, 2016				
	>A> 6284767	Feb 14, 2016	U-401			
	>A> 6284767*PED	Aug 14, 2016				

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<u>LOPINAVIR; RITONAVIR - KALETRA</u>						
021251 001	>A> 5914332	Dec 13, 2015	U-351			
	>A> 5914332*PED	Jun 13, 2016				
	>A> 6284767	Feb 14, 2016	U-401			
	>A> 6284767*PED	Aug 14, 2016				
<u>LOPINAVIR; RITONAVIR - KALETRA</u>						
021906 001	>A> 5914332	Dec 13, 2015	DS DP U-688			
	>A> 5914332*PED	Jun 13, 2016				
	>A> 6284767	Feb 14, 2016	DP U-688			
	>A> 6284767*PED	Aug 14, 2016				
	>A> 7148359	Jul 19, 2019	DP			
	>A> 7148359*PED	Jan 19, 2020				
<u>LOPINAVIR; RITONAVIR - KALETRA</u>						
021906 002	>A> 5541206	Jul 30, 2013	DS DP U-688			
	>A> 5541206*PED	Jan 30, 2014				
	>A> 5635523	Jun 03, 2014	U-688			
	>A> 5635523*PED	Dec 03, 2014				
	>A> 5648497	Jul 15, 2014	DS DP			
	>A> 5648497*PED	Jan 15, 2015				
	>A> 5674882	Oct 07, 2014	U-688			
	>A> 5674882*PED	Apr 07, 2015				
	>A> 5846987	Dec 29, 2012	U-688			
	>A> 5846987*PED	Jun 29, 2013				
	>A> 5886036	Nov 19, 2013	DS DP			
	>A> 5886036*PED	May 19, 2014				
	>A> 5914332	Dec 13, 2015	DS DP U-688			
	>A> 5914332*PED	Jun 13, 2016				
	>A> 6037157	Jun 26, 2016	U-688			
	>A> 6037157*PED	Dec 26, 2016				
	>A> 6284767	Feb 14, 2016	DP U-688			
	>A> 6284767*PED	Aug 14, 2016				
	>A> 6703403	Jun 26, 2016	U-688			
	>A> 6703403*PED	Dec 26, 2016				
	>A> 7148359	Jul 19, 2019	DP			
	>A> 7148359*PED	Jan 19, 2020				
<u>LOSARTAN POTASSIUM - COZAAR</u>						
020386 001	>A> 5608075	Mar 04, 2014		Y		
<u>LOSARTAN POTASSIUM - COZAAR</u>						
020386 002	>A> 5608075	Mar 04, 2014		Y		
<u>LOSARTAN POTASSIUM - COZAAR</u>						
020386 003	>A> 5608075	Mar 04, 2014		Y		
<u>MENTHOL; METHYL SALICYLATE - SALONPAS</u>						
022029 001					NDF NC	Feb 20, 2011 Feb 20, 2011

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<u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u>						
021410 001	>A> 5741803	Apr 21, 2015	DS DP U-734	Y		
	>A> 5741803	Apr 21, 2015	DS DP U-493	Y		
	>A> 5965584	Jun 19, 2016	U-493	Y		
	>A> 6166042	Jun 19, 2016	U-493	Y		
	>A> 6288095	Feb 11, 2017	U-493	Y		
<u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u>						
021410 002	>A> 5741803	Apr 21, 2015	DS DP U-734	Y		
	>A> 5741803	Apr 21, 2015	DS DP U-493	Y		
	>A> 5965584	Jun 19, 2016	U-493	Y		
	>A> 6166042	Jun 19, 2016	U-493	Y		
	>A> 6288095	Feb 11, 2017	U-493	Y		
<u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u>						
021410 003	>A> 5741803	Apr 21, 2015	DS DP U-734	Y		
	>A> 5741803	Apr 21, 2015	DS DP U-493	Y		
	>A> 5965584	Jun 19, 2016	U-493	Y		
	>A> 6166042	Jun 19, 2016	U-493	Y		
	>A> 6288095	Feb 11, 2017	U-493	Y		
<u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u>						
021410 004	>A> 5741803	Apr 21, 2015	DS DP U-734	Y		
	>A> 5741803	Apr 21, 2015	DS DP U-493	Y		
<u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u>						
021410 005	>A> 5741803	Apr 21, 2015	DS DP U-734	Y		
	>A> 5741803	Apr 21, 2015	DS DP U-493	Y		
<u>METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE - JANUMET</u>						
022044 001	7326708	Apr 11, 2026	DS DP U-802			
<u>METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE - JANUMET</u>						
022044 002	7326708	Apr 11, 2026	DS DP U-802			
<u>MICAFUNGIN SODIUM - MYCAMINE</u>						
021506 002	6107458	Sep 29, 2015	DS DP U-845		I-554	Jan 22, 2011
	6107458	Sep 29, 2015	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
	6107458	Sep 29, 2015	DS DP U-845		NCE	Mar 16, 2010
	6107458	Sep 29, 2015	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	>A> 4911932	Mar 27, 2009	DP U-718			

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



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<u>NISOLDIPINE - SULAR</u>						
020356 005	5422123	Jun 06, 2012	DP			
	5626874	Nov 30, 2014	DP			
<u>NISOLDIPINE - SULAR</u>						
020356 006	5422123	Jun 06, 2012	DP			
	5626874	Nov 30, 2014	DP			
<u>NISOLDIPINE - SULAR</u>						
020356 007	5422123	Jun 06, 2012	DP			
	5626874	Nov 30, 2014	DP			
<u>NISOLDIPINE - SULAR</u>						
020356 008	5422123	Jun 06, 2012	DP			
	5626874	Nov 30, 2014	DP			
<u>OLMESARTAN MEDOXOMIL - BENICAR</u>						
021286 001	>A> 6878703	Nov 19, 2021	U-3	Y		
<u>OLMESARTAN MEDOXOMIL - BENICAR</u>						
021286 003	>A> 6878703	Nov 19, 2021	U-3	Y		
<u>OLMESARTAN MEDOXOMIL - BENICAR</u>						
021286 004	>A> 6878703	Nov 19, 2021	U-3	Y		
<u>OMEPRAZOLE MAGNESIUM - PRILOSEC</u>						
022056 001					>A> NPP >A> PED	Mar 20, 2011 Sep 20, 2011
<u>OMEPRAZOLE MAGNESIUM - PRILOSEC</u>						
022056 002					>A> NPP >A> PED	Mar 20, 2011 Sep 20, 2011
<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					>A> NDF	Jun 22, 2009
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
021610 006					>A> NDF	Jun 22, 2009
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
021610 007					>A> NDF	Jun 22, 2009
<u>PALONOSETRON HYDROCHLORIDE - ALOXI</u>						
021372 002					>A> I-556 >A> NS >A> NCE	Mar 01, 2011 Mar 01, 2011 Jul 25, 2008
<u>PANTOPRAZOLE SODIUM - PANTOPRAZOLE SODIUM</u>						
077056 001					PC	Jun 18, 2008
<u>PANTOPRAZOLE SODIUM - PANTOPRAZOLE SODIUM</u>						
077056 002					PC	Jun 18, 2008
<u>PANTOPRAZOLE SODIUM - PANTOPRAZOLE SODIUM</u>						
077058 001					PC	Jun 18, 2008

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<u>PANTOPRAZOLE SODIUM - PANTOPRAZOLE SODIUM</u>						
077058 002					PC	Jun 18, 2008
<u>PANTOPRAZOLE SODIUM - PROTONIX</u>						
022020 001	>A> 4758579	Jul 19, 2010	DS DP U-859			
<u>PEMETREXED DISODIUM - ALIMTA</u>						
021462 002	5217974	Mar 29, 2011	U-551			
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>						
020667 001	>A> 4886812	Oct 08, 2010	DS DP			
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>						
020667 002	>A> 4886812	Oct 08, 2010	DS DP			
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>						
020667 003	>A> 4886812	Oct 08, 2010	DS DP			
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>						
020667 004	>A> 4886812	Oct 08, 2010	DS DP			
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>						
020667 005	>A> 4886812	Oct 08, 2010	DS DP			
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>						
020667 006	>A> 4886812	Oct 08, 2010	DS DP			
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>						
020667 007	>A> 4886812	Oct 08, 2010	DS DP		I-517	Nov 07, 2009
	6001861	Jan 16, 2018	U-784			
	6194445	Jan 16, 2018	U-784			
<u>PREDNISOLONE ACETATE - FLO-PRED</u>						
022067 001	5881926	Mar 16, 2016	DP			
	6071523	Jun 03, 2018	DP			
	6102254	Mar 11, 2013	DP			
	6399079	Jun 03, 2018	DP			
	6656482	Jun 03, 2018	DP			
<u>PREDNISOLONE ACETATE - FLO-PRED</u>						
022067 002	5881926	Mar 16, 2016	DP			
	6071523	Jun 03, 2018	DP			
	6102254	Mar 11, 2013	DP			
	6399079	Jun 03, 2018	DP			
	6656482	Jun 03, 2018	DP			
<u>PROGESTERONE - ENDOMETRIN</u>						
022057 001	>A> 7300664	Nov 17, 2019	U-856			
	>A> 7320800	Nov 17, 2019	U-856			
<u>RALOXIFENE HYDROCHLORIDE - EVISTA</u>						
020815 001	>A> 5393763	Jul 28, 2012	U-114	Y	>A> ODE	Sep 13, 2014
	>A> 5457117	Jul 28, 2012	U-114	Y		
	>A> 5478847	Mar 02, 2014	U-114	Y		
<u>RISPERIDONE - RISPERDAL</u>						
020588 001	>A> 5616587	Jul 11, 2014		Y		

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>ROCURONIUM BROMIDE - ZEMURON</u>						
020214 001	>A> 4894369	Apr 13, 2008				
	>A> 4894369*PED	Oct 13, 2008				
<u>ROCURONIUM BROMIDE - ZEMURON</u>						
020214 002	>A> 4894369	Apr 13, 2008				
	>A> 4894369*PED	Oct 13, 2008				
<u>ROCURONIUM BROMIDE - ZEMURON</u>						
020214 003	>A> 4894369	Apr 13, 2008				
	>A> 4894369*PED	Oct 13, 2008				
<u>ROSIGLITAZONE MALEATE - AVANDIA</u>						
021071 002	>A> 5741803	Apr 21, 2015	DS DP U-628	Y		
	>A> 5741803	Apr 21, 2015	DS DP U-329	Y		
	>A> 6288095	Feb 11, 2017	U-420	Y		
<u>ROSIGLITAZONE MALEATE - AVANDIA</u>						
021071 003	>A> 5741803	Apr 21, 2015	DS DP U-628	Y		
	>A> 5741803	Apr 21, 2015	DS DP U-329	Y		
	>A> 6288095	Feb 11, 2017	U-420	Y		
<u>ROSIGLITAZONE MALEATE - AVANDIA</u>						
021071 004	>A> 5741803	Apr 21, 2015	DS DP U-628	Y		
	>A> 5741803	Apr 21, 2015	DS DP U-329	Y		
	>A> 6288095	Feb 11, 2017	U-420	Y		
<u>SEVELAMER CARBONATE - RENVELA</u>						
022127 001	5496545	Aug 11, 2013	DP U-246			
	5667775	Sep 16, 2014	U-246			
	6509013	Aug 11, 2013	DP			
	6858203	Aug 11, 2013	DP U-246			
	7014846	Aug 11, 2013	DP U-246			
<u>SIROLIMUS - RAPAMUNE</u>						
021110 001	>A> 5145684	Jan 25, 2011	DP U-857			
	>A> 5145684*PED	Jul 25, 2011				
<u>SIROLIMUS - RAPAMUNE</u>						
021110 002	>A> 5145684	Jan 25, 2011	DP U-857			
	>A> 5145684*PED	Jul 25, 2011				
<u>SIROLIMUS - RAPAMUNE</u>						
021110 003	>A> 5145684	Jan 25, 2011	DP U-857			
	>A> 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			

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<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					>A> ODE	Nov 16, 2014
<u>SUMATRIPTAN SUCCINATE - IMITREX</u>						
020132 001	>A> 5863559	Jan 26, 2016	U-72	Y		
	>A> 6020001	Mar 02, 2012	U-444	Y		
	>A> 6368627	Mar 02, 2012	U-444	Y		
<u>SUMATRIPTAN SUCCINATE - IMITREX</u>						
020132 002	>A> 5863559	Jan 26, 2016	U-72	Y		
	>A> 6020001	Mar 02, 2012	U-444	Y		
	>A> 6368627	Mar 02, 2012	U-444	Y		
<u>SUMATRIPTAN SUCCINATE - IMITREX</u>						
020132 003	>A> 5863559	Jan 26, 2016	U-72	Y		
	>A> 6020001	Mar 02, 2012	U-444	Y		
	>A> 6368627	Mar 02, 2012	U-444	Y		
<u>SUMATRIPTAN SUCCINATE - IMITREX STATDOSE</u>						
020080 002	5037845	Aug 06, 2008	DS DP U-848			
	5037845*PED	Feb 06, 2009				
<u>TADALAFIL - CIALIS</u>						
021368 001					D-111	Jan 07, 2011
<u>TADALAFIL - CIALIS</u>						
021368 004	5859006	Nov 21, 2017	DS DP		D-111	Jan 07, 2011
	6140329	Jul 11, 2016	DP U-155		NCE	Nov 21, 2008
	6821975	Nov 19, 2020	DS DP U-614			
	6821975	Nov 19, 2020	DS DP U-533			
	6943166	Apr 26, 2020	U-155			
	7182958	Apr 26, 2020	DP U-155			
<u>TECHNETIUM TC-99M SESTAMIBI KIT - CARDIOLITE</u>						
019785 001	4988827	Jan 29, 2008				
	4988827*PED	Jul 29, 2008				
<u>TERBINAFINE - LAMISIL AT</u>						
021958 001	6121314	May 18, 2012	U-540			
	6121314	May 18, 2012	U-504			
<u>TESTOSTERONE - TESTIM</u>						
021454 001	7320968	Jan 18, 2025	U-843			
<u>TIGECYCLINE - TYGACIL</u>						
021821 001	5494903	Apr 09, 2016	DS DP			
	>A> RE40086	Jun 25, 2013	U-282			

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 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>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	>A> 5852195	Jun 22, 2019	DS		>A> NCE	Jun 22, 2010
	>A> 5852195*PED	Dec 22, 2019			>A> PED	Dec 22, 2010
	>A> 6147095	Oct 29, 2019	U-670			
	>A> 6147095*PED	Apr 29, 2020				
	>A> 6169181	May 06, 2014	DS			
	>A> 6169181*PED	Nov 06, 2014				
	>A> 6231887	Jul 27, 2018	DP			
	>A> 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			

## 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.
3. Patent number 4904769 listed on all products of NDA 20482 Precose (Acarbose) was requested to be delisted by the sponsor on 4/16/2007. This patent has remained listed because, under Section 505(j)(5)(D)(i) of the Act, a first applicant may retain eligibility for 180-day exclusivity based on a paragraph IV certification to this patent for a certain period.

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

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

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

## PATENT AND EXCLUSIVITY TERMS

Due to space limitations in the patent and exclusivity columns, abbreviations and references have been developed. Refer to the APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 28<sup>th</sup> Edition for a full listing of patent and exclusivity terms (Abbreviations, Dosing Schedule, Indications, and Patent Use Codes).

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