

APPROVED DRUG PRODUCTS

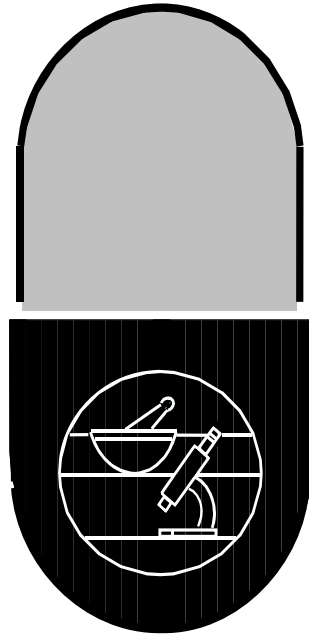
With Therapeutic Equivalence Evaluations



The "Orange Book"

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**CUMULATIVE
SUPPLEMENT 02
February 2008**



**APPROVED
DRUG PRODUCTS**

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

28th 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**

28th EDITION

Cumulative Supplement 02

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28th EDITION

**CUMULATIVE SUPPLEMENT 02
February 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, 27th 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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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.
 - o Refer to CS Section 1.8 Cumulative Supplement Legend for types of changes
 - o 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. 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)

1.4 AVAILABILITY OF THE EDITION

Since 1997, the Electronic Orange Book Query (EOBQ) <http://www.fda.gov/cder/ob/default.htm>, has been available on the internet and has become the updated-every-month Orange Book. The Query provides searching of the approved drug list by active ingredient, proprietary name, applicant holder, applicant number or patent number. Product search categories are: prescription, over-the-counter, discontinued drugs. There are links to patent and exclusivity information that may be applicable to each product.

Commencing with the 25th edition, the Annual Edition and monthly Cumulative Supplements have been provided in downloadable Portable Document Format (PDF) at the EOB home page by clicking on Annual

Edition. The PDF annual and cumulative supplements duplicate previous paper versions. Over time, there will be an archive for the annuals and each year's December Cumulative Supplement.

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

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

There are ASCII text files of the Orange Book drug product, patent, and exclusivity data at <http://www.fda.gov/cder/orange/obreadme.htm>. The drug product text files are provided in eobzip.exe and eobzip.zip format. The files are updated concurrently with the monthly cumulative supplements. The annual Orange Book Edition Appendices A, B, and C in PDF format are updated quarterly. Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from the FDA Forms List, <http://www.fda.gov/opacom/morechoices/fdaforms/default.html>.

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

1.5 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

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

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

DEFINITIONS

Drug Product

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

New Molecular Entity

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

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

<u>CATEGORIES COUNTED</u>	<u>DEC 2007</u>	<u>MAR 2007</u>	<u>JUN 2007</u>	<u>SEPT 2007</u>
DRUG PRODUCTS LISTED	12302	12063	11900	12130
SINGLE SOURCE	2489 (20.2%)	2471 (20.5%)	2483 (20.9%)	2494 (20.6%)
MULTISOURCE	9724 (79.0%)	9503 (78.8%)	9328 (78.4%)	9547 (78.7%)
THERAPEUTICALLY EQUIVALENT	9571 (77.8%)	9320 (77.3%)	9148 (76.9%)	9394 (77.4%)
NOT THERAPEUTICALLY EQUIVALENT	153 (1.2%)	183 (1.5%)	180 (1.5%)	153 (1.3%)
EXCEPTIONS ¹	89 (0.7%)	89 (0.7%)	89 (0.7%)	89 (0.7%)
NEW MOLECULAR ENTITIES APPROVED	7	4	7	10
NUMBER OF APPLICANTS	693	675	679	683

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

1.6 CUMULATIVE SUPPLEMENT LEGEND

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

The individual product record contains the Therapeutic Equivalence Code, Reference Listed Drug symbol, applicant holder, strength(s), New Drug 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 2 - February 2008

1-1

ACEBUTOLOL HYDROCHLORIDE

CAPSULE; ORAL

ACEBUTOLOL HYDROCHLORIDE

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

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

>D>	AA	MUTUAL PHARM	300MG;15MG	N89671 001	Feb 10, 1988	Feb	DISC
>A>		@	300MG;15MG	N89671 001	Feb 10, 1988	Feb	DISC

ACETAMINOPHEN; HYDROCODONE BITARTRATE

SOLUTION; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

>D>	AA	+	MIKART	500MG/15ML;5MG/15ML	N89557 001	Apr 29, 1992	Feb	DISC
>A>			@	500MG/15ML;5MG/15ML	N89557 001	Apr 29, 1992	Feb	DISC

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

TABLET; ORAL

PERCOCET

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

>D>	AB		BARR	250MG	N70869 001	Feb 09, 1987	Feb	DISC
>A>			@	250MG	N70869 001	Feb 09, 1987	Feb	DISC
			@	500MG	N70870 001	Feb 09, 1987	Jan	DISC
>D>	AB		WATSON LABS	250MG	N71893 001	Nov 25, 1987	Feb	CTEC
>A>				250MG	N71893 001	Nov 25, 1987	Feb	CTEC
		+		500MG	N71894 001	Nov 25, 1987	Jan	CRLD

ACYCLOVIR

CAPSULE; ORAL

ACYCLOVIR

>D>	AB		APOTHECON	200MG	N74889 001	Oct 31, 1997	Feb	DISC
>A>			@	200MG	N74889 001	Oct 31, 1997	Feb	DISC

TABLET; ORAL

ACYCLOVIR

>D>	AB		APOTHECON	400MG	N74891 001	Oct 31, 1997	Feb	DISC
>A>			@	400MG	N74891 001	Oct 31, 1997	Feb	DISC
>D>	AB			800MG	N74891 002	Oct 31, 1997	Feb	DISC

		TABLET; ORAL							
		ACYCLOVIR							
>A>		@ APOTHECON	800MG	N74891	002	Oct 31,	1997	Feb	DISC

ALBUTEROL SULFATE

		SYRUP; ORAL							
		ALBUTEROL SULFATE							
>D>	AA	ACTAVIS MID ATLANTIC	EQ 2MG BASE/5ML	N75262	001	Mar 30,	1999	Feb	DISC
>A>		@	EQ 2MG BASE/5ML	N75262	001	Mar 30,	1999	Feb	DISC
		TABLET; ORAL							
		ALBUTEROL SULFATE							
>D>	AB	WATSON LABS	EQ 4MG BASE	N72630	001	Jan 31,	1991	Feb	DISC
>A>		@	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							
		TEKTURN 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

ALPRAZOLAM

		TABLET; ORAL							
		ALPRAZOLAM							
>D>	AB	TEVA	0.25MG	N74085	001	Feb 16,	1994	Feb	DISC
>A>		@	0.25MG	N74085	001	Feb 16,	1994	Feb	DISC
>D>	AB		0.5MG	N74085	002	Feb 16,	1994	Feb	DISC
>A>		@	0.5MG	N74085	002	Feb 16,	1994	Feb	DISC
>D>	AB		1MG	N74085	003	Feb 16,	1994	Feb	DISC
>A>		@	1MG	N74085	003	Feb 16,	1994	Feb	DISC
>D>	AB		2MG	N74085	004	Feb 26,	1996	Feb	DISC
>A>		@	2MG	N74085	004	Feb 26,	1996	Feb	DISC

AMANTADINE HYDROCHLORIDE

		SYRUP; ORAL							
		AMANTADINE HYDROCHLORIDE							
>D>	AA	+	TEVA PHARMS	50MG/5ML	N73115	001	Aug 23,	1991	Feb
>A>		@		50MG/5ML	N73115	001	Aug 23,	1991	Feb

AMIODARONE HYDROCHLORIDE

INJECTABLE; INJECTION

AMIODARONE HYDROCHLORIDE

>A>	AP	HIKMA FARMACEUTICA	50MG/ML	N77234 001	Feb 25, 2008	Feb	NEWA
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TABLET; ORAL

AMIODARONE HYDROCHLORIDE

>D>	AB	TEVA	200MG	N74895 001	Apr 16, 1999	Feb	DISC
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>A>		@	200MG	N74895 001	Apr 16, 1999	Feb	DISC
-----	--	---	-------	------------	--------------	-----	------

AMLODIPINE BESYLATE

TABLET; ORAL

AMLODIPINE BESYLATE

>D>	AB	GENPHARM	EQ 2.5MG BASE	N77362 001	Jul 09, 2007	Feb	DISC
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>A>		@	EQ 2.5MG BASE	N77362 001	Jul 09, 2007	Feb	DISC
-----	--	---	---------------	------------	--------------	-----	------

>D>	AB		EQ 5MG BASE	N77362 002	Jul 09, 2007	Feb	DISC
-----	----	--	-------------	------------	--------------	-----	------

>A>		@	EQ 5MG BASE	N77362 002	Jul 09, 2007	Feb	DISC
-----	--	---	-------------	------------	--------------	-----	------

>D>	AB		EQ 10MG BASE	N77362 003	Jul 09, 2007	Feb	DISC
-----	----	--	--------------	------------	--------------	-----	------

>A>		@	EQ 10MG BASE	N77362 003	Jul 09, 2007	Feb	DISC
-----	--	---	--------------	------------	--------------	-----	------

	AB	INTERPHARM	EQ 2.5MG BASE	N78477 001	Jan 16, 2008	Jan	NEWA
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	AB		EQ 5MG BASE	N78477 002	Jan 16, 2008	Jan	NEWA
--	----	--	-------------	------------	--------------	-----	------

	AB		EQ 10MG BASE	N78477 003	Jan 16, 2008	Jan	NEWA
--	----	--	--------------	------------	--------------	-----	------

>A>	AB	MATRIX LABS LTD	EQ 2.5MG BASE	N78224 001	Feb 27, 2008	Feb	NEWA
-----	----	-----------------	---------------	------------	--------------	-----	------

>A>	AB		EQ 5MG BASE	N78224 002	Feb 27, 2008	Feb	NEWA
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>A>	AB		EQ 10MG BASE	N78224 003	Feb 27, 2008	Feb	NEWA
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	AB	MUTUAL PHARMA	EQ 2.5MG BASE	N78081 001	Jan 31, 2008	Jan	NEWA
--	----	---------------	---------------	------------	--------------	-----	------

	AB		EQ 5MG BASE	N78081 002	Jan 31, 2008	Jan	NEWA
--	----	--	-------------	------------	--------------	-----	------

	AB		EQ 10MG BASE	N78081 003	Jan 31, 2008	Jan	NEWA
--	----	--	--------------	------------	--------------	-----	------

AMOXICILLIN

TABLET, EXTENDED RELEASE; ORAL

MOXATAG

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

INJECTABLE; INJECTION

TENORMIN

>D>							
-----	--	--	--	--	--	--	--

>D>	+	ASTRAZENECA	0.5MG/ML	N19058 001	Sep 13, 1989	Feb	DISC
-----	---	-------------	----------	------------	--------------	-----	------

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

ATENOLOL

>D>	AB	PLIVA	25MG	N74101 001	Jul 17, 1997	Feb	DISC
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>A>		@	25MG	N74101 001	Jul 17, 1997	Feb	DISC
-----	--	---	------	------------	--------------	-----	------

>D>	AB		50MG	N74101 002	Jul 17, 1997	Feb	DISC
-----	----	--	------	------------	--------------	-----	------

>A>		@	50MG	N74101 002	Jul 17, 1997	Feb	DISC
-----	--	---	------	------------	--------------	-----	------

>D>	AB		100MG	N74101 003	Jul 17, 1997	Feb	DISC
-----	----	--	-------	------------	--------------	-----	------

>A>		@	100MG	N74101 003	Jul 17, 1997	Feb	DISC
-----	--	---	-------	------------	--------------	-----	------

>D>	AB	SANDOZ	25MG	N74265 001	Feb 28, 1994	Feb	DISC
-----	----	--------	------	------------	--------------	-----	------

>A>		@	25MG	N74265 001	Feb 28, 1994	Feb	DISC
-----	--	---	------	------------	--------------	-----	------

>D>	AB		50MG	N74265 002	Feb 28, 1994	Feb	DISC
-----	----	--	------	------------	--------------	-----	------

>A>		@	50MG	N74265 002	Feb 28, 1994	Feb	DISC
-----	--	---	------	------------	--------------	-----	------

>D>	AB		100MG	N74265 003	Feb 28, 1994	Feb	DISC
-----	----	--	-------	------------	--------------	-----	------

>A>		@	100MG	N74265 003	Feb 28, 1994	Feb	DISC
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>D>	AB	SCS	50MG	N73676 001	Oct 30, 1992	Feb	DISC
-----	----	-----	------	------------	--------------	-----	------

>A>		@	50MG	N73676 001	Oct 30, 1992	Feb	DISC
-----	--	---	------	------------	--------------	-----	------

>D>	AB		100MG	N73676 002	Oct 30, 1992	Feb	DISC
-----	----	--	-------	------------	--------------	-----	------

TABLET; ORAL

ATENOLOL

>A>	@ SCS	100MG	N73676 002	Oct 30, 1992	Feb	DISC
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ATROPINE SULFATE; EDROPHONIUM CHLORIDE

INJECTABLE; INJECTION

ENLON-PLUS

>D>	ENLON-PLUS					
>D>	+	BAXTER HLTHCARE CORP	0.14MG/ML;10MG/ML	N19677 001	Nov 06, 1991	Feb DISC
>A>	@		0.14MG/ML;10MG/ML	N19677 001	Nov 06, 1991	Feb DISC
>D>	+		0.14MG/ML;10MG/ML	N19678 001	Nov 06, 1991	Feb DISC
>A>	@		0.14MG/ML;10MG/ML	N19678 001	Nov 06, 1991	Feb DISC

AZITHROMYCIN

TABLET; ORAL

AZITHROMYCIN

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

AZTREONAM

INJECTABLE; INJECTION

AZACTAM

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

TABLET; ORAL

NADOLOL AND BENDROFLUMETHAZIDE

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

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
>D>	AA	MUTUAL PHARM	1MG	N81264 001	Jan 23, 1992	Feb DISC
>A>	@		1MG	N81264 001	Jan 23, 1992	Feb DISC
>D>	AA		2MG	N81265 001	Jan 23, 1992	Feb DISC
>A>	@		2MG	N81265 001	Jan 23, 1992	Feb DISC

BLEOMYCIN SULFATE

INJECTABLE; INJECTION

BLEOMYCIN SULFATE

AP	ABRAXIS PHARM	EQ 15 UNITS BASE/VIAL	N65185 001	Jan 28, 2008	Jan	NEWA
AP		EQ 30 UNITS BASE/VIAL	N65185 002	Jan 28, 2008	Jan	NEWA
AP	BEDFORD	EQ 15 UNITS BASE/VIAL	N65042 002	Oct 17, 2001	Jan	CTNA
AP		EQ 30 UNITS BASE/VIAL	N65042 001	Oct 17, 2001	Jan	CTNA
AP	HOSPIRA	EQ 15 UNITS BASE/VIAL	N65031 001	Mar 10, 2000	Jan	CTNA

INJECTABLE; INJECTIONBLEOMYCIN SULFATE

AP	HOSPIRA	EQ 30 UNITS BASE/VIAL	N65031 002	Mar 10, 2000	Jan	CTNA
AP	PHARMACHEMIE BV	EQ 15 UNITS BASE/VIAL	N65201 001	Dec 13, 2007	Jan	CTNA
AP	TEVA PARENTERAL	EQ 15 UNITS BASE/VIAL	N65033 001	Jun 27, 2000	Jan	CTNA
AP		EQ 30 UNITS BASE/VIAL	N65033 002	Jun 27, 2000	Jan	CTNA

BRIMONIDINE TARTRATESOLUTION/DROPS; OPHTHALMICBRIMONIDINE TARTRATE

AT	SANDOZ	0.2%	N78075 001	Jan 30, 2008	Jan	NEWA
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>D> BROMODIPHENHYDRAMINE HYDROCHLORIDE; CODEINE PHOSPHATE>D> SYRUP; ORAL>D> BROMODIPHENHYDRAMINE HYDROCHLORIDE AND CODEINE PHOSPHATE

>A>	@ MORTON GROVE	12.5MG/5ML;10MG/5ML	N88626 001	Oct 12, 1984	Feb	DISC
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>D> MYBANIL

>D>	+ MORTON GROVE	12.5MG/5ML;10MG/5ML	N88626 001	Oct 12, 1984	Feb	DISC
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BUPROPION HYDROCHLORIDETABLET, EXTENDED RELEASE; ORALBUPROPION HYDROCHLORIDE

>A>	AB1 ACTAVIS	150MG	N77475 001	Mar 12, 2008	Feb	NEWA
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CAFFEINE CITRATESOLUTION; ORALCAFFEINE CITRATE

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

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

CALCIUM ACETATECAPSULE; ORAL>A> CALCIUM ACETATE

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

>D>	+ FRESENIUS MEDCL	EQ 169MG CALCIUM	N21160 003	Apr 02, 2001	Feb	CFTG
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>A>	AB +	EQ 169MG CALCIUM	N21160 003	Apr 02, 2001	Feb	CFTG
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TABLET; ORALCALCIUM ACETATE

	+ ROXANE	EQ 169MG CALCIUM	N77693 001	Jan 30, 2008	Jan	NEWA
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CAPTOPRILTABLET; ORALCAPTOPRIL

>D>	AB SANDOZ	12.5MG	N74481 001	Feb 13, 1996	Feb	DISC
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>A>	@	12.5MG	N74481 001	Feb 13, 1996	Feb	DISC
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>D>	AB	12.5MG	N74519 001	Feb 13, 1996	Feb	DISC
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>A>	@	12.5MG	N74519 001	Feb 13, 1996	Feb	DISC
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>D>	AB	25MG	N74481 002	Feb 13, 1996	Feb	DISC
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>A>	@	25MG	N74481 002	Feb 13, 1996	Feb	DISC
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TABLET; ORAL

CAPTOPRIL

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

CARBINOXAMINE MALEATE

SOLUTION; ORAL

CARBINOXAMINE MALEATE

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

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

CEFTRIAZONE SODIUM

INJECTABLE; IM-IV

CEFTRIAZONE

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

CEFUROXIME AXETIL

FOR SUSPENSION; ORAL

CEFTIN

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

CEFUROXIME AXETIL

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

TABLET; ORAL

CEFUROXIME AXETIL

AB	ORCHID HLTHCARE	EQ 125MG BASE	N65359 001	Feb 15, 2008	Jan	NEWA
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TABLET; ORAL

CEFUROXIME AXETIL

AB	ORCHID HLTHCARE	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

ZYTEC

+	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 HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

CIPROFLOXACIN HYDROCHLORIDE

AT	PHARMAFORCE	EQ 0.3% BASE	N78598 001	Jan 16, 2008	Jan	NEWA
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CLOBETASOL PROPIONATE

AEROSOL, FOAM; TOPICAL

>A>		CLOBETASOL PROPIONATE				
>A>	AB	PERRIGO ISRAEL	0.05%	N77763 001	Mar 10, 2008	Feb NEWA
		OLUX				
>D>	+	CONNETICS	0.05%	N21142 001	May 26, 2000	Feb CFTG
>A>	AB	+	0.05%	N21142 001	May 26, 2000	Feb CFTG

CLOPIDOGREL BISULFATE

TABLET; ORAL

CLOPIDOGREL BISULFATE

AB	DR REDDYS LABS INC	EQ 75MG BASE	N76273 001	Jan 14, 2008	Jan	NEWA
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CODEINE PHOSPHATE; PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

SYRUP; ORAL

TRIACIN-C

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

COSYNTROPIN

SOLUTION; INTRAVENOUS

COSYNTROPIN

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

TABLET; ORAL

CYCLOBENZAPRINE HYDROCHLORIDE

>D>	AB	SANDOZ	10MG	N73683 001	Feb 26, 1993	Feb DISC
>A>		@	10MG	N73683 001	Feb 26, 1993	Feb DISC
>D>	AB	WATSON LABS	10MG	N73143 001	Nov 27, 1991	Feb DISC
>A>		@	10MG	N73143 001	Nov 27, 1991	Feb DISC

TABLET; ORAL

CYCLOBENZAPRINE HYDROCHLORIDE

>D>	AB	WATSON LABS	10MG	N74436 001	Nov 30, 1994	Feb	DISC
>A>		@	10MG	N74436 001	Nov 30, 1994	Feb	DISC

CYCLOPHOSPHAMIDE

INJECTABLE; INJECTION

CYCLOPHOSPHAMIDE

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

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

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

DEMECLOCYCLINE HYDROCHLORIDE

TABLET; ORAL

DEMECLOCYCLINE HYDROCHLORIDE

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

>A> DESVENLAFAXINE SUCCINATE

>A> TABLET, EXTENDED RELEASE; ORAL

>A> PRISTIQ

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

DEXAMETHASONE

ELIXIR; ORAL

DEXAMETHASONE

>A>	AA	+	MORTON GROVE	0.5MG/5ML	N88254 001	Jul 27, 1983	Feb	CTNA
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		ELIXIR; ORAL					
>D>		MYMETHASONE					
>D>	AA	+	MORTON GROVE 0.5MG/5ML	N88254	001	Jul 27, 1983	Feb CTNA
<u>DEXCHLORPHENIRAMINE MALEATE</u>							
		SYRUP; ORAL					
>A>		DEXCHLORPHENIRAMINE MALEATE					
>A>		+	MORTON GROVE 2MG/5ML	N88251	001	Mar 23, 1984	Feb CTNA
>D>		MYLARAMINE					
>D>		+	MORTON GROVE 2MG/5ML	N88251	001	Mar 23, 1984	Feb CTNA
		TABLET; ORAL					
>D>		DEXCHLORPHENIRAMINE MALEATE					
>D>		+	PLIVA 2MG	N88682	001	Jan 17, 1986	Feb DISC
>A>		@	2MG	N88682	001	Jan 17, 1986	Feb DISC
<u>DEXTROAMPHETAMINE SULFATE</u>							
		SOLUTION; ORAL					
		DEXTROAMPHETAMINE SULFATE					
		+	OUTLOOK PHARMS 5MG/5ML	N40776	001	Jan 29, 2008	Jan NEWA
<u>DIAZEPAM</u>							
		INJECTABLE; INJECTION					
		DIAZEPAM					
>D>	AP		MARSAM PHARMS LLC 5MG/ML	N72397	001	Jan 29, 1993	Feb DISC
>A>		@	5MG/ML	N72397	001	Jan 29, 1993	Feb DISC
<u>DICLOFENAC SODIUM</u>							
		GEL; TOPICAL					
		SOLARAZE					
>D>		+	BIOGLAN PHARMS CORP 3%	N21005	001	Oct 16, 2000	Feb CAHN
>A>		+	NYCOMED US 3%	N21005	001	Oct 16, 2000	Feb CAHN
		SOLUTION/DROPS; OPHTHALMIC					
		DICLOFENAC SODIUM					
AT			ALCON 0.1%	N78031	001	Feb 06, 2008	Jan NEWA
<u>DICLOXACILLIN SODIUM</u>							
		FOR SUSPENSION; ORAL					
		DICLOXACILLIN SODIUM					
		@	APOTHECON EQ 62.5MG BASE/5ML	N61455	001		Jan DISC
<u>DILTIAZEM HYDROCHLORIDE</u>							
		INJECTABLE; INJECTION					
		DILTIAZEM HYDROCHLORIDE					
>D>	AP		HOSPIRA 5MG/ML	N75004	001	Feb 16, 2000	Feb DISC
>A>		@	5MG/ML	N75004	001	Feb 16, 2000	Feb DISC
<u>DIPHENHYDRAMINE HYDROCHLORIDE</u>							
		CAPSULE; ORAL					
		DIPHENHYDRAMINE HYDROCHLORIDE					
>D>	AA		MUTUAL PHARM 25MG	N84506	001		Feb DISC
>A>		@	25MG	N84506	001		Feb DISC
>D>	AA		25MG	N89488	001	Jan 02, 1987	Feb DISC
>A>		@	25MG	N89488	001	Jan 02, 1987	Feb DISC

DIPYRIDAMOLE

TABLET; ORAL

DIPYRIDAMOLE

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

DOBUTAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

DOBUTAMINE HYDROCHLORIDE

>D>	AP	MARSAM PHARMS LLC	EQ 12.5MG BASE/ML	N74995 001	Mar 31, 1998	Feb	DISC
>A>		@	EQ 12.5MG BASE/ML	N74995 001	Mar 31, 1998	Feb	DISC

DOXEPIN HYDROCHLORIDE

CREAM; TOPICAL

ZONALON

>D>	+	BRADLEY PHARMS	5%	N20126 001	Apr 01, 1994	Feb	CAHN
>A>	+	NYCOMED US	5%	N20126 001	Apr 01, 1994	Feb	CAHN

ECONAZOLE NITRATE

CREAM; TOPICAL

SPECTAZOLE

>D>		@ JOHNSON AND JOHNSON	1%	N18751 001	Dec 23, 1982	Feb	CAHN
>A>		@ ORTHONEUTROGENA	1%	N18751 001	Dec 23, 1982	Feb	CAHN

EDETATE DISODIUM

INJECTABLE; INJECTION

EDETATE DISODIUM

@ APOTEX INC 150MG/ML

N40376 001 Nov 04, 2002 Jan DISC

EDROPHONIUM CHLORIDE

INJECTABLE; INJECTION

ENLON

>D>							
>D>	AP	BAXTER HLTHCARE CORP	10MG/ML	N88873 001	Aug 06, 1985	Feb	DISC
>A>		@	10MG/ML	N88873 001	Aug 06, 1985	Feb	DISC

ERYTHROMYCIN

SWAB; TOPICAL

ERYCETTE

>D>		@ J AND J	2%	N50594 001	Feb 15, 1985	Feb	CAHN
>A>		@ ORTHONEUTROGENA	2%	N50594 001	Feb 15, 1985	Feb	CAHN

ESOMEPRAZOLE MAGNESIUM

FOR SUSPENSION, DELAYED RELEASE; ORAL

NEXIUM

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

GEL, METERED; TRANSDERMAL

ELESTRIN

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

GEL, METERED; TRANSDERMAL

ESTROGEL

+	ASCEND	0.06% (1.25GM/ACTIVATION)	N21166 002	Feb 09, 2004	Jan	CTEC
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ETHAMBUTOL HYDROCHLORIDE

TABLET; ORAL

MYAMBUTOL

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

ETRAVIRINE

TABLET; ORAL

INTELENCE

+	TIBOTEC	100MG	N22187 001	Jan 18, 2008	Jan	NEWA
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FAMOTIDINE

INJECTABLE; INJECTION

FAMOTIDINE

>D>	AP	APOTEX INC	10MG/ML	N75942 001	Aug 02, 2002	Feb	DISC
>A>		@	10MG/ML	N75942 001	Aug 02, 2002	Feb	DISC
>D>	AP	HOSPIRA	10MG/ML	N75905 001	Nov 23, 2001	Feb	DISC
>A>		@	10MG/ML	N75905 001	Nov 23, 2001	Feb	DISC

TABLET; ORAL

FAMOTIDINE

>D>	AB	SANDOZ	20MG	N75793 001	Apr 16, 2001	Feb	DISC
>A>		@	20MG	N75793 001	Apr 16, 2001	Feb	DISC
>D>	AB		40MG	N75793 002	Apr 16, 2001	Feb	DISC
>A>		@	40MG	N75793 002	Apr 16, 2001	Feb	DISC

FENOPROFEN CALCIUM

TABLET; ORAL

FENOPROFEN CALCIUM

>D>	AB	WATSON LABS	EQ 600MG BASE	N72407 001	Aug 17, 1988	Feb	DISC
>A>		@	EQ 600MG BASE	N72407 001	Aug 17, 1988	Feb	DISC
>D>	AB		EQ 600MG BASE	N72602 001	Oct 11, 1988	Feb	DISC
>A>		@	EQ 600MG BASE	N72602 001	Oct 11, 1988	Feb	DISC

FLECAINIDE ACETATE

TABLET; ORAL

FLECAINIDE ACETATE

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

FLUOCINONIDE

CREAM; TOPICAL

FLUOCINONIDE

>D>	AB1	TARO	0.05%	N71500 001	Jun 10, 1987	Feb	DISC
>A>		@	0.05%	N71500 001	Jun 10, 1987	Feb	DISC

		SOLUTION; TOPICAL						
		FLUOCINONIDE						
>D>	AT	TARO	0.05%	N72857 001	Aug 02, 1989	Feb	DISC	
>A>		@	0.05%	N72857 001	Aug 02, 1989	Feb	DISC	
<u>FLUOXETINE HYDROCHLORIDE</u>								
		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	
<u>FLUTICASONE PROPIONATE</u>								
		SPRAY, METERED; NASAL						
		FLUTICASONE PROPIONATE						
AB		HI TECH PHARMA	0.05MG/SPRAY	N77570 001	Jan 16, 2008	Jan	NEWA	
<u>FLUVOXAMINE MALEATE</u>								
>A>		CAPSULE, EXTENDED RELEASE; ORAL						
>A>		LUVOX CR						
>A>		SOLVAY	100MG	N22033 001	Feb 28, 2008	Feb	NEWA	
>A>		+	150MG	N22033 002	Feb 28, 2008	Feb	NEWA	
<u>FOMEPIZOLE</u>								
		INJECTABLE; INJECTION						
		FOMEPIZOLE						
>A>	AP	NAVINTA LLC	1.5GM/1.5ML (1GM/ML)	N78537 001	Mar 06, 2008	Feb	NEWA	
>A>	AP	SYNERX PHARMA	1.5GM/1.5ML (1GM/ML)	N78639 001	Mar 03, 2008	Feb	NEWA	
<u>FOSAPREPITANT DIMEGLUMINE</u>								
		POWDER; INTRAVENOUS						
		EMEND						
		+	MERCK AND CO INC	EQ 115MG BASE/VIAL	N22023 001	Jan 25, 2008	Jan	NEWA
<u>GABAPENTIN</u>								
		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	
<u>GLIPIZIDE; METFORMIN HYDROCHLORIDE</u>								
		TABLET; ORAL						
		GLIPIZIDE AND METFORMIN HYDROCHLORIDE						
AB		CARACO	2.5MG;250MG	N77620 001	Jan 11, 2008	Jan	NEWA	
AB			2.5MG;500MG	N77620 002	Jan 11, 2008	Jan	NEWA	
AB			5MG;500MG	N77620 003	Jan 11, 2008	Jan	NEWA	
<u>GRANISETRON HYDROCHLORIDE</u>								
		INJECTABLE; INJECTION						
		GRANISETRON HYDROCHLORIDE						
>A>	AP	WOCKHARDT USA	EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML)	N78566 001	Feb 29, 2008	Feb	NEWA	

SOLUTION; ORAL

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

TABLET; ORAL

		GRANISETRON HYDROCHLORIDE							
>A>	AB	APOTEX INC	EQ 1MG BASE	N78843	001	Feb 27, 2008	Feb	NEWA	
>A>	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							
>D>	AB	+	J AND J	125MG/5ML	N62483	001	Jan 26, 1984	Feb	CAHN
>A>	AB	+	ORTHONEUTROGENA	125MG/5ML	N62483	001	Jan 26, 1984	Feb	CAHN

TABLET; ORAL

		GRIFULVIN V							
>D>		J AND J	125MG	N62279	001		Feb	CAHN	
>D>	AB		250MG	N62279	002		Feb	CAHN	
>D>	AB		500MG	N62279	003		Feb	CAHN	
>A>		ORTHONEUTROGENA	125MG	N62279	001		Feb	CAHN	
>A>	AB		250MG	N62279	002		Feb	CAHN	
>A>	AB		500MG	N62279	003		Feb	CAHN	

GUANFACINE HYDROCHLORIDE

TABLET; ORAL

		GUANFACINE HYDROCHLORIDE							
>A>	AB	AMNEAL PHARM	EQ 1MG BASE	N75109	001	Nov 25, 1998	Feb	CAHN	
>A>	AB		EQ 2MG BASE	N75109	002	Nov 25, 1998	Feb	CAHN	
>D>	AB	GENPHARM	EQ 1MG BASE	N75109	001	Nov 25, 1998	Feb	CAHN	
>D>	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	
>A>	AA	MORTON GROVE	1.5MG/5ML;5MG/5ML	N88008	001	Mar 03, 1983	Feb	CTNA	
>D>		MYCODONE							
>D>	AA	MORTON GROVE	1.5MG/5ML;5MG/5ML	N88008	001	Mar 03, 1983	Feb	CTNA	

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

		HYDRALAZINE HYDROCHLORIDE							
>D>	AA	MUTUAL PHARM	10MG	N89359	001	Jul 25, 1986	Feb	DISC	
>A>		@	10MG	N89359	001	Jul 25, 1986	Feb	DISC	
>D>	AA		25MG	N89258	001	May 05, 1986	Feb	DISC	
>A>		@	25MG	N89258	001	May 05, 1986	Feb	DISC	

TABLET; ORAL

HYDRALAZINE HYDROCHLORIDE

>D>	AA	MUTUAL PHARM	50MG	N89259 001	May 05, 1986	Feb	DISC
>A>		@	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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HYDROXYZINE

TABLET; ORAL

HYDROXYZINE HYDROCHLORIDE

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

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL

IMIPRAMINE HYDROCHLORIDE

>A>	AB	ACTAVIS TOTOWA	10MG	N40753 001	Feb 28, 2008	Feb	NEWA
>A>	AB		25MG	N40752 001	Feb 28, 2008	Feb	NEWA
>A>	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

INDOMETHACIN

CAPSULE; ORAL

INDOCIN

>A>	@	IROKO PHARMS	25MG	N16059 001		Feb	CAHN
>A>	@		50MG	N16059 002		Feb	CAHN
>D>	@	MERCK	25MG	N16059 001		Feb	CAHN
>D>	@		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

>A>	@	IROKO PHARMS	75MG	N18185 001	Feb 23, 1982	Feb	CAHN
>D>	@	MERCK	75MG	N18185 001	Feb 23, 1982	Feb	CAHN

SUPPOSITORY; RECTAL

INDOCIN

>A>	@ IROKO PHARMS	50MG	N17814 001	Aug 13, 1984	Feb	CAHN
>D>	@ MERCK	50MG	N17814 001	Aug 13, 1984	Feb	CAHN

IRINOTECAN HYDROCHLORIDE

INJECTABLE; INJECTION

CAMPTOSAR

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

IRINOTECAN HYDROCHLORIDE

>A>	AP	ACTAVIS TOTOWA	40MG/2ML (20MG/ML)	N78589 001	Feb 27, 2008	Feb	NEWA
>A>	AP		100MG/5ML (20MG/ML)	N78589 002	Feb 27, 2008	Feb	NEWA
>A>	AP	APP PHARMS	40MG/2ML (20MG/ML)	N77776 001	Feb 27, 2008	Feb	NEWA
>A>	AP		100MG/5ML (20MG/ML)	N77776 002	Feb 27, 2008	Feb	NEWA
>A>	AP	DABUR ONCOLOGY PLC	40MG/2ML (20MG/ML)	N78188 001	Feb 27, 2008	Feb	NEWA
>A>	AP		100MG/5ML (20MG/ML)	N78188 002	Feb 27, 2008	Feb	NEWA
>A>	AP	HOSPIRA	40MG/2ML (20MG/ML)	N77915 001	Feb 27, 2008	Feb	NEWA
>A>	AP		100MG/5ML (20MG/ML)	N77915 002	Feb 27, 2008	Feb	NEWA
>A>	+		500MG/25ML (20MG/ML)	N78796 001	Feb 27, 2008	Feb	NEWA
>A>	AP	SANDOZ	40MG/2ML (20MG/ML)	N77994 001	Feb 27, 2008	Feb	NEWA
>A>	AP		100MG/5ML (20MG/ML)	N77994 002	Feb 27, 2008	Feb	NEWA
>A>	AP	TEVA PARENTERAL	40MG/2ML (20MG/ML)	N77260 001	Feb 27, 2008	Feb	NEWA
>A>	AP		100MG/5ML (20MG/ML)	N77260 002	Feb 27, 2008	Feb	NEWA
>A>	AP	WATSON LABS	40MG/2ML (20MG/ML)	N77219 001	Feb 20, 2008	Feb	NEWA
>A>	AP		100MG/5ML (20MG/ML)	N77219 002	Feb 20, 2008	Feb	NEWA

ISOSORBIDE DINITRATE

TABLET; SUBLINGUAL

ISOSORBIDE DINITRATE

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

>D>	+	ALZA	EQ 65MG BASE	N21088 001	Mar 03, 2000	Feb	CAHN
>A>	+	JOHNSON AND JOHNSON	EQ 65MG BASE	N21088 001	Mar 03, 2000	Feb	CAHN

LEVOCETIRIZINE DIHYDROCHLORIDE

SOLUTION; ORAL

XYZAL

+	UCB INC	2.5MG/5ML	N22157 001	Jan 28, 2008	Jan	NEWA
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LEVONORDEFIN; MEPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION

POLOCAINE W/ LEVONORDEFIN

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

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

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
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UNITHROID

>A>	AB1, AB2, AB3	STEVENS J	0.137MG	N21210 012	Feb 08, 2008	Feb	NEWA
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LITHIUM CARBONATE

CAPSULE; ORAL

ESKALITH

AB	NOVEN THERAP	300MG	N16860 001		Jan	CAHN
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TABLET, EXTENDED RELEASE; ORAL

LITHOBID

AB +	NOVEN THERAP	300MG	N18027 001		Jan	CAHN
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MELOXICAM

TABLET; ORAL

MELOXICAM

>D>	AB	ROXANE	7.5MG	N77925 001	Jul 19, 2006	Feb	DISC
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>A>	@		7.5MG	N77925 001	Jul 19, 2006	Feb	DISC
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>D>	AB		15MG	N77925 002	Jul 19, 2006	Feb	DISC
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>A>	@		15MG	N77925 002	Jul 19, 2006	Feb	DISC
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MEPROBAMATE

TABLET; ORAL

MEPROBAMATE

>A>	AA	INVAGEN PHARMS	200MG	N40797 001	Feb 27, 2008	Feb	NEWA
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>A>	AA		400MG	N40797 002	Feb 27, 2008	Feb	NEWA
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>D>	+	WATSON LABS	400MG	N83308 001		Feb	CTEC
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>A>	AA +		400MG	N83308 001		Feb	CTEC
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METAPROTERENOL SULFATE

SYRUP; ORAL

METAPROTERENOL SULFATE

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

TABLET; ORAL

PAMINE

>D>	AA +	BRADLEY PHARMS	2.5MG	N08848 001		Feb	CAHN
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>A>	AA +	NYCOMED US	2.5MG	N08848 001		Feb	CAHN
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PAMINE FORTE

>D>	AA +	BRADLEY PHARMS	5MG	N08848 002	Mar 25, 2003	Feb	CAHN
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>A>	AA +	NYCOMED US	5MG	N08848 002	Mar 25, 2003	Feb	CAHN
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METOCLOPRAMIDE HYDROCHLORIDE

SOLUTION; ORAL

METOCLOPRAMIDE HYDROCHLORIDE

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

MICONAZOLE NITRATE

CREAM; TOPICAL

MONISTAT-DERM

>D>		+	JOHNSON AND JOHNSON	2%	N17494 001		Feb	CAHN
>A>		+	ORTHONEUTROGENA	2%	N17494 001		Feb	CAHN

MINOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL

MINOCYCLINE HYDROCHLORIDE

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

TABLET; ORAL

MINOCYCLINE HYDROCHLORIDE

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

MINOXIDIL

TABLET; ORAL

LONITEN

@ PHARMACIA AND UPJOHN 2.5MG

@ 10MG

N18154 001 Jan DISC

N18154 003 Jan DISC

MOMETASONE FUROATE

POWDER; INHALATION

ASMANEX TWISTHALER

>A>			SCHERING	0.11MG/INH	N21067 002	Feb 01, 2008	Feb	NEWA
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MUPIROCI

OINTMENT; TOPICAL

CENTANY

>D>	BX		JOHNSON AND JOHNSON	2%	N50788 001	Dec 04, 2002	Feb	CAHN
>A>	BX		ORTHONEUTROGENA	2%	N50788 001	Dec 04, 2002	Feb	CAHN

NABUMETONE

TABLET; ORAL

NABUMETONE

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

NIACIN; SIMVASTATIN

>A>	TABLET, EXTENDED RELEASE; ORAL							
>A>	SIMCOR							
>A>	ABBOTT	500MG;20MG		N22078	001	Feb 15,	2008	Feb NEWA
>A>		750MG;20MG		N22078	002	Feb 15,	2008	Feb NEWA
>A>	+	1GM;20MG		N22078	003	Feb 15,	2008	Feb NEWA

NICARDIPINE HYDROCHLORIDE

	CAPSULE; ORAL							
	NICARDIPINE HYDROCHLORIDE							
>A>	AB	AMNEAL PHARM	20MG	N74928	001	Mar 19,	1998	Feb CAHN
>A>	AB		30MG	N74928	002	Mar 19,	1998	Feb CAHN
>D>	AB	GENPHARM	20MG	N74928	001	Mar 19,	1998	Feb CAHN
>D>	AB		30MG	N74928	002	Mar 19,	1998	Feb CAHN

NIMODIPINE

	CAPSULE; ORAL							
	NIMODIPINE							
AB		BANNER PHARMACAPS	30MG	N76740	001	Jan 17,	2008	Jan NEWA

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

NYSTATIN

	TABLET; ORAL							
	NYSTATIN							
AA	+	TEVA	500,000 UNITS	N62506	001	Jan 16,	1984	Jan CRLD

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
>A>	AP	SUN PHARM INDS	EQ 0.05MG BASE/ML	N77329	001	Mar 04,	2008	Feb NEWA
>A>	AP		EQ 0.1MG BASE/ML	N77329	002	Mar 04,	2008	Feb NEWA
>A>	AP		EQ 0.2MG BASE/ML	N77330	001	Mar 04,	2008	Feb NEWA
>A>	AP		EQ 0.5MG BASE/ML	N77329	003	Mar 04,	2008	Feb NEWA
>A>	AP		EQ 1MG BASE/ML	N77331	001	Mar 04,	2008	Feb NEWA

OXYCODONE HYDROCHLORIDE

	TABLET, EXTENDED RELEASE; ORAL							
	OXYCODONE HYDROCHLORIDE							
>D>	AB	IMPAX LABS	80MG	N76318	001	Sep 27,	2004	Feb DISC
>A>	@		80MG	N76318	001	Sep 27,	2004	Feb DISC

TABLET, EXTENDED RELEASE; ORAL

OXYCODONE HYDROCHLORIDE

>D>	AB	IMPAX PHARMS	10MG	N76446 001	Dec 06, 2005	Feb	DISC
>A>		@	10MG	N76446 001	Dec 06, 2005	Feb	DISC
>D>	AB		20MG	N76446 002	Dec 06, 2005	Feb	DISC
>A>		@	20MG	N76446 002	Dec 06, 2005	Feb	DISC
>D>	AB		40MG	N76446 003	Dec 06, 2005	Feb	DISC
>A>		@	40MG	N76446 003	Dec 06, 2005	Feb	DISC
>D>	AB	TEVA	10MG	N76610 001	Dec 06, 2005	Feb	DISC
>A>		@	10MG	N76610 001	Dec 06, 2005	Feb	DISC
>D>	AB		20MG	N76610 002	Dec 06, 2005	Feb	DISC
>A>		@	20MG	N76610 002	Dec 06, 2005	Feb	DISC
>D>	AB		40MG	N76610 003	Dec 06, 2005	Feb	DISC
>A>		@	40MG	N76610 003	Dec 06, 2005	Feb	DISC
>D>	AB		80MG	N76168 001	Mar 23, 2004	Feb	DISC
>A>		@	80MG	N76168 001	Mar 23, 2004	Feb	DISC

OXYCONTIN

>D>	AB	PURDUE PHARMA LP	10MG	N20553 001	Dec 12, 1995	Feb	CTEC
>A>			10MG	N20553 001	Dec 12, 1995	Feb	CTEC
			15MG	N20553 006	Sep 18, 2006	Jan	CMFD
>D>	AB		20MG	N20553 002	Dec 12, 1995	Feb	CTEC
>A>			20MG	N20553 002	Dec 12, 1995	Feb	CTEC
			30MG	N20553 007	Sep 18, 2006	Jan	CMFD
>D>	AB	+	40MG	N20553 003	Dec 12, 1995	Feb	CTEC
>A>		+	40MG	N20553 003	Dec 12, 1995	Feb	CTEC
			60MG	N20553 008	Sep 18, 2006	Jan	CMFD
>D>	AB		80MG	N20553 004	Jan 06, 1997	Feb	CTEC
>A>			80MG	N20553 004	Jan 06, 1997	Feb	CTEC

OXYMORPHONE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

OPANA ER

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

OXYTOCIN

INJECTABLE; INJECTION

OXYTOCIN

AP	+	APP PHARMS	100USP UNITS/10 ML (10USP UNITS/ML)	N18248 002		Jan	CFTG
AP		TEVA PARENTERAL	10USP UNITS/ML (10USP UNITS/ML)	N77453 001	Jan 24, 2008	Jan	NEWA
AP			100USP UNITS/10ML (10USP UNITS/ML)	N77453 002	Jan 24, 2008	Jan	NEWA

INJECTABLE; INTRAMUSCULAR, IV (INFUSION)

OXYTOCIN

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

INJECTABLE; INJECTION

PACLITAXEL

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

TABLET, EXTENDED RELEASE; ORAL

INVEGA

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

PALONOSETRON HYDROCHLORIDE

INJECTABLE; INTRAVENOUS

ALOXI

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

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

PHENDIMETRAZINE TARTRATE

AA	AMIDE PHARM	35MG	N40762 001	Jan 28, 2008	Jan	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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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

>D>	BOEHRINGER INGELHEIM	0.125MG	N20667 001	Jul 01, 1997	Feb	CFTG
>A>	AB	0.125MG	N20667 001	Jul 01, 1997	Feb	CFTG
>D>	+	0.25MG	N20667 002	Jul 01, 1997	Feb	CFTG
>A>	AB	0.25MG	N20667 002	Jul 01, 1997	Feb	CFTG
>D>		0.5MG	N20667 006	Feb 12, 1998	Feb	CFTG
>A>	AB	0.5MG	N20667 006	Feb 12, 1998	Feb	CFTG
>D>		1MG	N20667 003	Jul 01, 1997	Feb	CFTG
>A>	AB	1MG	N20667 003	Jul 01, 1997	Feb	CFTG
>D>		1.5MG	N20667 005	Jul 01, 1997	Feb	CFTG
>A>	AB	1.5MG	N20667 005	Jul 01, 1997	Feb	CFTG

PRAMIPEXOLE DIHYDROCHLORIDE

>A>	AB	BARR	0.125MG	N77724 001	Feb 19, 2008	Feb	NEWA
>A>	AB		0.25MG	N77724 002	Feb 19, 2008	Feb	NEWA
>A>	AB		0.5MG	N77724 003	Feb 19, 2008	Feb	NEWA
>A>	AB		1MG	N77724 004	Feb 19, 2008	Feb	NEWA
>A>	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
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		TABLET; ORAL							
		PRAVASTATIN SODIUM							
AB		TEVA PHARMS	80MG		N77793 001	Jan 15, 2008	Jan	NEWA	
		<u>PREDNISOLONE ACETATE</u>							
		SUSPENSION; ORAL							
		FLO-PRED							
		TARO	EQ 5MG BASE/5ML		N22067 001	Jan 17, 2008	Jan	NEWA	
		+	EQ 15MG BASE/5ML		N22067 002	Jan 17, 2008	Jan	NEWA	
		<u>PREDNISOLONE SODIUM PHOSPHATE</u>							
		SOLUTION; ORAL							
		PREDNISOLONE SODIUM PHOSPHATE							
>A>	AA	PHARM ASSOC	EQ 10MG BASE/5ML		N78465 001	Mar 07, 2008	Feb	NEWA	
		<u>PRIMIDONE</u>							
		TABLET; ORAL							
		PRIMIDONE							
AB		IMPAX LABS	50MG		N40717 001	Feb 12, 2008	Jan	NEWA	
AB			250MG		N40717 002	Feb 12, 2008	Jan	NEWA	
		<u>PROCHLORPERAZINE EDISYLATE</u>							
		INJECTABLE; INJECTION							
		PROCHLORPERAZINE EDISYLATE							
		@ TEVA PARENTERAL	EQ 5MG BASE/ML		N40505 001	May 30, 2003	Jan	DISC	
		<u>PROMETHAZINE HYDROCHLORIDE</u>							
		TABLET; ORAL							
>D>		PHENERGAN							
>D>	AB	WYETH PHARMS INC	25MG		N07935 003		Feb	DISC	
>A>		@	25MG		N07935 003		Feb	DISC	
		PROMETHAZINE HYDROCHLORIDE							
>A>	AB	ACTAVIS TOTOWA	12.5MG		N40673 001	Mar 05, 2008	Feb	NEWA	
>A>	AB		25MG		N40673 002	Mar 05, 2008	Feb	NEWA	
>A>	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	
		<u>PROPRANOLOL HYDROCHLORIDE</u>							
		INJECTABLE; INJECTION							
		PROPRANOLOL HYDROCHLORIDE							
AP		HIKMA FARMACEUTICA	1MG/ML		N77760 001	Jan 31, 2008	Jan	NEWA	
		<u>SERTACONAZOLE NITRATE</u>							
		CREAM; TOPICAL							
		ERTACZO							
>D>	+	JOHNSON AND JOHNSON	2%		N21385 001	Dec 10, 2003	Feb	CAHN	
>A>	+	ORTHONEUTROGENA	2%		N21385 001	Dec 10, 2003	Feb	CAHN	
		<u>SERTRALINE HYDROCHLORIDE</u>							
		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

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

SODIUM IODIDE, I-131

CAPSULE; ORAL

>A>		HICON					
>A>		DRAXIMAGE	100uCi	N21305 004	Nov 18, 2004	Feb	CTNA
>D>		SODIUM IODIDE I 131					
>D>		DRAXIMAGE	100uCi	N21305 004	Nov 18, 2004	Feb	CTNA

SOLUTION; ORAL

>A>		HICON					
>A>	+	DRAXIMAGE	1-250mCi/0.25ML	N21305 002	Jan 24, 2003	Feb	CTNA
>A>	+		1-500mCi/0.5ML	N21305 003	Jan 24, 2003	Feb	CTNA
>D>		SODIUM IODIDE I 131, KIT					
>D>	+	DRAXIMAGE	1-500mCi/0.5ML	N21305 003	Jan 24, 2003	Feb	CTNA
>D>	+		1-250mCi/0.25ML	N21305 002	Jan 24, 2003	Feb	CTNA

SOMATROPIN RECOMBINANT

INJECTABLE; INJECTION

ACCRETROPIN

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

SOTALOL HYDROCHLORIDE

TABLET; ORAL

SOTALOL HYDROCHLORIDE

>A>	AB2	AMNEAL PHARM	80MG	N77070 001	Nov 04, 2005	Feb	CAHN
>A>	AB2		120MG	N77070 002	Nov 04, 2005	Feb	CAHN
>A>	AB2		160MG	N77070 003	Nov 04, 2005	Feb	CAHN
>D>	AB2	GENPHARM	80MG	N77070 001	Nov 04, 2005	Feb	CAHN
>D>	AB2		120MG	N77070 002	Nov 04, 2005	Feb	CAHN
>D>	AB2		160MG	N77070 003	Nov 04, 2005	Feb	CAHN

TADALAFIL

TABLET; ORAL

CIALIS

LILLY

2.5MG

N21368 004 Jan 07, 2008 Jan NEWA

TECHNETIUM TC-99M MEBROFENIN KIT

INJECTABLE; INJECTION

CHOLETEC

AP + BRACCO N/A

N18963 001 Jan 21, 1987 Jan CFTG

TECHNETIUM TC-99M MEBROFENIN

AP CIS N/A

N78242 001 Jan 29, 2008 Jan NEWA

TERAZOSIN HYDROCHLORIDE

CAPSULE; ORAL

TERAZOSIN HYDROCHLORIDE

>D> AB MYLAN TECHNOLOGIES EQ 1MG BASE

N75384 001 Dec 01, 2000 Feb DISC

>A> @ EQ 1MG BASE

N75384 001 Dec 01, 2000 Feb DISC

>D> AB EQ 2MG BASE

N75384 002 Dec 01, 2000 Feb DISC

>A> @ EQ 2MG BASE

N75384 002 Dec 01, 2000 Feb DISC

>D> AB EQ 5MG BASE

N75384 003 Dec 01, 2000 Feb DISC

>A> @ EQ 5MG BASE

N75384 003 Dec 01, 2000 Feb DISC

>D> AB EQ 10MG BASE

N75384 004 Dec 01, 2000 Feb DISC

>A> @ EQ 10MG BASE

N75384 004 Dec 01, 2000 Feb DISC

>D> TESTOLACTONE

>D> TABLET; ORAL

>D> TESLAC

>D> + BRISTOL MYERS SQUIBB 50MG

N16118 001 Feb DISC

>A> @ 50MG

N16118 001 Feb DISC

THEOPHYLLINE

TABLET, EXTENDED RELEASE; ORAL

UNIPHYL

>D> AB PURDUE FREDERICK 400MG

N87571 001 Sep 01, 1982 Feb CAHN

>D> AB + 600MG

N40086 001 Apr 15, 1996 Feb CAHN

>A> AB PURDUE PHARM PRODS 400MG

N87571 001 Sep 01, 1982 Feb CAHN

>A> AB + 600MG

N40086 001 Apr 15, 1996 Feb CAHN

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL

THIORIDAZINE HYDROCHLORIDE

>D> AB MUTUAL PHARM 50MG

N88370 001 Nov 18, 1983 Feb DISC

>A> @ 50MG

N88370 001 Nov 18, 1983 Feb DISC

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION

TOBRAMYCIN

>D> APP PHARMS EQ 1.2GM BASE/VIAL

N50789 001 Jul 13, 2004 Feb CTEC

>A> AP EQ 1.2GM BASE/VIAL

N50789 001 Jul 13, 2004 Feb CTEC

>D> + X GEN PHARMS EQ 1.2GM BASE/VIAL

N65013 001 Aug 17, 2001 Feb CTEC

>A> AP + EQ 1.2GM BASE/VIAL

N65013 001 Aug 17, 2001 Feb CTEC

TOBRAMYCIN SULFATE

>A> AP AKORN STRIDES EQ 40MG BASE/ML

N65407 001 Mar 11, 2008 Feb NEWA

TORSEMIDE

TABLET; ORAL

TORSEMIDE

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

VALPROIC ACID

SYRUP; ORAL

>D>		MYPROIC ACID					
>D>	AA	MORTON GROVE	250MG/5ML	N70868 001	Jul 01, 1986	Feb	CTNA
>A>		VALPROIC ACID					
>A>	AA	MORTON GROVE	250MG/5ML	N70868 001	Jul 01, 1986	Feb	CTNA

VARDENAFIL HYDROCHLORIDE

TABLET; ORAL

LEVITRA

BAYER HLTHCARE

+

2.5MG

5MG

10MG

20MG

N21400 003 Aug 19, 2003 Jan CAHN

N21400 001 Aug 19, 2003 Jan CAHN

N21400 002 Aug 19, 2003 Jan CAHN

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

ZIDOVUDINE

TABLET; ORAL

ZIDOVUDINE

AB MATRIX LABS LTD 300MG

N78922 001 Feb 14, 2008 Jan NEWA

ZILEUTON

TABLET; ORAL

ZYFLO

>D> + CRITICAL 600MG

N20471 003 Dec 09, 1996 Feb DISC

>A> @ 600MG

N20471 003 Dec 09, 1996 Feb DISC

OTC DRUG PRODUCT LIST - 28TH EDITION

OTC DRUG PRODUCT LIST - CUMULATIVE SUPPLMENT 2 - February 2008

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CALCIUM CARBONATE; FAMOTIDINE; MAGNESIUM HYDROXIDE

TABLET, CHEWABLE; ORAL

CALCIUM CARBONATE, FAMOTIDINE AND MAGNESIUM HYDROXIDE

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

CETIRIZINE HYDROCHLORIDE

SYRUP; ORAL

CHILDREN'S ZYRTEC ALLERGY

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

CHILDREN'S ZYRTEC HIVES RELIEF

+ MCNEIL CONSUMER 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

CETIRIZINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE

>A> SANDOZ 5MG;120MG N77991 001 Mar 05, 2008 Feb NEWA

>A> 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

>A> MENTHOL; METHYL SALICYLATE

>A> PATCH; TOPICAL

>A> SALONPAS

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

POTASSIUM IODIDE

TABLET; ORAL

THYROSAFE

+ RECIP 65MG N76350 001 Sep 10, 2002 Jan CAHN

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

CUMULATIVE SUPPLEMENT NUMBER 02 FEBRUARY 2008

NO FEBRUARY 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 FEBRUARY 2008 ADDITIONS

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST - 28TH EDITION

A - 1

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

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>ADEFOVIR DIPIVOXIL - HEPSERA</u>					
021449 001				>A> NPP	Dec 19, 2010
<u>ALENDRONATE SODIUM - ALENDRONATE SODIUM</u>					
075710 003				>A> PC	Aug 04, 2008
<u>ALENDRONATE SODIUM - ALENDRONATE SODIUM</u>					
076184 001				>A> PC	Aug 04, 2008
<u>ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE - TEKTURN HCT</u>					
022107 001				>A> NCE >A> NC	Mar 05, 2012 Jan 18, 2011
<u>ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE - TEKTURN HCT</u>					
022107 002				>A> NCE >A> NC	Mar 05, 2012 Jan 18, 2011
<u>ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE - TEKTURN HCT</u>					
022107 003				>A> NCE >A> NC	Mar 05, 2012 Jan 18, 2011
<u>ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE - TEKTURN HCT</u>					
022107 004				>A> NCE >A> NC	Mar 05, 2012 Jan 18, 2011
<u>APREPITANT - EMEND</u>					
021549 001	>A> 5719147 >A> 7214692	Apr 17, 2015 Sep 18, 2012	DS DP	U-853 U-853	
<u>APREPITANT - EMEND</u>					
021549 002	>A> 7214692	Sep 18, 2012		U-853	
<u>APREPITANT - EMEND</u>					
021549 003	>A> 7214692	Sep 18, 2012		U-853	
<u>ARFORMOTEROL TARTRATE - BROVANA</u>					
021912 001	>A> 6040344 >A> 6472563 >A> 6720453 >A> 7145036	Nov 12, 2016 Nov 09, 2021 Nov 09, 2021 Nov 09, 2021	DS DS DS DS		
<u>ARIPIPRAZOLE - ABILIFY</u>					
021436 001				>A> D-110 >A> I-555 >A> PED >A> PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>					
021436 002				>A> D-110 >A> I-555 >A> PED >A> PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>					
021436 003				>A> D-110 >A> I-555 >A> PED >A> PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>					
021436 004				>A> D-110 >A> I-555 >A> PED >A> PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>					
021436 005				>A> D-110 >A> I-555 >A> PED >A> PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011

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

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>ARIPIPRAZOLE - ABILIFY</u>					
021436	006			>A> D-110 >A> I-555 >A> PED >A> PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>					
021713	001			>A> D-110 >A> I-555 >A> PED >A> PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>					
021729	002			>A> D-110 >A> I-555 >A> PED >A> PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>					
021729	003			>A> D-110 >A> I-555 >A> PED >A> PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>					
021729	004			>A> D-110 >A> I-555 >A> PED >A> PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>					
021729	005			>A> D-110 >A> I-555 >A> PED >A> PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>ARIPIPRAZOLE - ABILIFY</u>					
021866	001			>A> D-110 >A> I-555 >A> PED >A> PED	Oct 29, 2010 Feb 27, 2011 Aug 27, 2011 Apr 29, 2011
<u>BRIMONIDINE TARTRATE; TIMOLOL MALEATE - COMBIGAN</u>					
021398	001	>A> 7030149	Apr 19, 2022	U-849	
		>A> 7030976	Apr 19, 2022	U-849	
		>A> 7323463	Jan 19, 2023	DP	
<u>CARVEDILOL - COREG</u>					
020297	001	>A> RE40000	Jun 07, 2015	U-233	
		>A> RE40000*PED	Dec 07, 2015		
<u>CARVEDILOL - COREG</u>					
020297	002	>A> RE40000	Jun 07, 2015	U-233	
		>A> RE40000*PED	Dec 07, 2015		
<u>CARVEDILOL - COREG</u>					
020297	003	>A> RE40000	Jun 07, 2015	U-233	
		>A> RE40000*PED	Dec 07, 2015		
<u>CARVEDILOL - COREG</u>					
020297	004	>A> RE40000	Jun 07, 2015	U-233	
		>A> RE40000*PED	Dec 07, 2015		
<u>CARVEDILOL PHOSPHATE - COREG CR</u>					
022012	001	>A> RE40000	Jun 07, 2015	U-777	
		>A> RE40000*PED	Dec 07, 2015		
<u>CARVEDILOL PHOSPHATE - COREG CR</u>					
022012	002	>A> RE40000	Jun 07, 2015	U-777	
		>A> RE40000*PED	Dec 07, 2015		

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>CARVEDILOL PHOSPHATE - COREG CR</u>					
022012 003	>A> RE40000	Jun 07, 2015	U-777		
	>A> RE40000*PED	Dec 07, 2015			
<u>CARVEDILOL PHOSPHATE - COREG CR</u>					
022012 004	>A> RE40000	Jun 07, 2015	U-777		
	>A> RE40000*PED	Dec 07, 2015			
<u>CICLESONIDE - ALVESCO</u>					
021658 002	>A> 5482934	Jan 09, 2013	DS DP	U-645	
	>A> 5482934	Jan 09, 2013	DS DP	U-675	
	>A> 5482934	Jan 09, 2013	DS DP	U-738	
	>A> 5482934	Jan 09, 2013	DS DP	U-754	
	>A> 5482934	Jan 09, 2013	DS DP	U-841	
	>A> 5482934	Jan 09, 2013	DS DP	U-228	
	>A> 5605674	Feb 25, 2014	DP		
	>A> 5683677	Nov 04, 2014	DP		
	>A> 5695743	Jul 06, 2010	DP	U-754	
	>A> 5695743	Jul 06, 2010	DP	U-228	
	>A> 5695743	Jul 06, 2010	DP	U-645	
	>A> 5695743	Jul 06, 2010	DP	U-738	
	>A> 5695743	Jul 06, 2010	DP	U-841	
	>A> 5695743	Jul 06, 2010	DP	U-675	
	>A> 5775321	Jul 07, 2015	DP		
	>A> 6006745	Dec 28, 2016	DP		
	>A> 6036942	Apr 30, 2013	DP		
	>A> 6120752	May 13, 2018	DP		
	>A> 6264923	May 13, 2013	DP		
<u>CICLESONIDE - ALVESCO</u>					
021658 003	>A> 5482934	Jan 09, 2013	DS DP	U-645	
	>A> 5482934	Jan 09, 2013	DS DP	U-675	
	>A> 5482934	Jan 09, 2013	DS DP	U-738	
	>A> 5482934	Jan 09, 2013	DS DP	U-754	
	>A> 5482934	Jan 09, 2013	DS DP	U-841	
	>A> 5482934	Jan 09, 2013	DS DP	U-228	
	>A> 5605674	Feb 25, 2014	DP		
	>A> 5683677	Nov 04, 2014	DP		
	>A> 5695743	Jul 06, 2010	DP	U-754	
	>A> 5695743	Jul 06, 2010	DP	U-228	
	>A> 5695743	Jul 06, 2010	DP	U-645	
	>A> 5695743	Jul 06, 2010	DP	U-738	
	>A> 5695743	Jul 06, 2010	DP	U-841	
	>A> 5695743	Jul 06, 2010	DP	U-675	
	>A> 5775321	Jul 07, 2015	DP		
	>A> 6006745	Dec 28, 2016	DP		
	>A> 6036942	Apr 30, 2013	DP		
	>A> 6120752	May 13, 2018	DP		
	>A> 6264923	May 13, 2013	DP		
<u>CLOFARABINE - CLOLAR</u>					
021673 001	>A> 5661136	Jan 14, 2018	U-626		
<u>COLESEVELAM HYDROCHLORIDE - WELCHOL</u>					
021176 001	>A> 5919832	Apr 29, 2014	DS	>A> I-553	Jan 18, 2011
	>A> 6066678	Apr 29, 2014	DS	U-323	
	>A> 6433026	Apr 29, 2014	DS		
	>A> 6784254	Apr 29, 2014	DS DP		
	>A> 7229613	Apr 17, 2022	U-851		
<u>DAPTOMYCIN - CUBICIN</u>					
021572 002	>A> RE39071	Jun 15, 2016	DS DP	U-728	
<u>DARIFENACIN HYDROBROMIDE - ENABLEX</u>					
021513 001	>A> 5096890	Mar 13, 2015	DS DP	U-631	

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<u>DARIFENACIN HYDROBROMIDE - ENABLEX</u>					
021513 002	>A> 5096890	Mar 13, 2015	DS DP U-631		
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>					
021976 002				>A> NCE	Jun 23, 2011
<u>DEXTROAMPHETAMINE SULFATE - DEXTROAMPHETAMINE SULFATE</u>					
076814 001				>A> PC	Aug 04, 2008
<u>ELETRIPTAN HYDROBROMIDE - RELPAX</u>					
021016 001	>A> 6110940	Aug 29, 2017			
<u>ELETRIPTAN HYDROBROMIDE - RELPAX</u>					
021016 002	>A> 6110940	Aug 29, 2017			
<u>ENTECAVIR - BARACLUDE</u>					
021797 001	>A> 5206244	Feb 21, 2015	DS		
<u>ENTECAVIR - BARACLUDE</u>					
021797 002	>A> 5206244	Feb 21, 2015	DS		
<u>ENTECAVIR - BARACLUDE</u>					
021798 001	>A> 5206244	Feb 21, 2015	DS		
<u>EPLERENONE - INSPRA</u>					
021437 001				>A> M-72 >A> PED	Jan 31, 2011 Jul 31, 2011
<u>EPLERENONE - INSPRA</u>					
021437 002				>A> M-72 >A> PED	Jan 31, 2011 Jul 31, 2011
<u>ESTRADIOL; NORGESTIMATE - PREFEST</u>					
021040 001	>A> 7320970	Mar 30, 2020	DP U-844		
<u>ETHINYL ESTRADIOL; LEVONORGESTREL - SEASONIQUE</u>					
021840 001	>A> 7320969	Jan 30, 2024	U-828		
<u>ETRAVIRINE - INTELENCE</u>					
022187 001				>A> NCE	Jan 18, 2013
<u>EXENATIDE SYNTHETIC - BYETTA</u>					
021773 001	>A> 5424286	Dec 01, 2016	U-653		
<u>EZETIMIBE - ZETIA</u>					
021445 001	>A> 5846966	Sep 21, 2013	U-474	>A> I-493	May 23, 2009
	>A> 5846966*PED	Mar 21, 2014		>A> PED	Nov 23, 2009
	>A> 7030106	Jan 25, 2022	DP		
	>A> 7030106*PED	Jul 25, 2022			
	>A> RE37721	Oct 25, 2016	DS DP U-473		
	>A> RE37721*PED	Apr 25, 2017			
<u>EZETIMIBE; SIMVASTATIN - VYTORIN</u>					
021687 001	>A> 5846966	Sep 21, 2013	DP U-593		
	>A> 5846966*PED	Mar 21, 2014			
	>A> RE37721	Oct 25, 2016	DS DP U-473		
	>A> RE37721*PED	Apr 25, 2017			
<u>EZETIMIBE; SIMVASTATIN - VYTORIN</u>					
021687 002	>A> 5846966	Sep 21, 2013	DP U-593		
	>A> 5846966*PED	Mar 21, 2014			
	>A> RE37721	Oct 25, 2016	DS DP U-473		
	>A> RE37721*PED	Apr 25, 2017			
<u>EZETIMIBE; SIMVASTATIN - VYTORIN</u>					
021687 003	>A> 5846966	Sep 21, 2013	DP U-593		
	>A> 5846966*PED	Mar 21, 2014			
	>A> RE37721	Oct 25, 2016	DS DP U-473		
	>A> RE37721*PED	Apr 25, 2017			

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<u>EZETIMIBE; SIMVASTATIN - VYTORIN</u>					
021687 004	>A> 5846966	Sep 21, 2013	DP U-593		
	>A> 5846966*PED	Mar 21, 2014			
	>A> RE37721	Oct 25, 2016	DS DP U-473		
	>A> RE37721*PED	Apr 25, 2017			
<u>FENOFIBRATE - TRICOR</u>					
021656 001	>A> 7320802	Feb 21, 2023		U-847	
<u>FENOFIBRATE - TRICOR</u>					
021656 002	>A> 7320802	Feb 21, 2023		U-847	
<u>FENTANYL CITRATE - FENTORA</u>					
021947 006	>A> 6200604	Mar 26, 2019		U-767	
	>A> 6974590	Mar 26, 2019		U-767	
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 100/50</u>					
021077 001	>A> RE40045	Sep 07, 2010	DP		
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 250/50</u>					
021077 002	>A> RE40045	Sep 07, 2010	DP		
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 500/50</u>					
021077 003	>A> RE40045	Sep 07, 2010	DP		
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR HFA</u>					
021254 001	>A> RE40045	Sep 07, 2010	DP		
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR HFA</u>					
021254 002	>A> RE40045	Sep 07, 2010	DP		
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR HFA</u>					
021254 003	>A> RE40045	Sep 07, 2010	DP		
<u>FLUVOXAMINE MALEATE - LUVOX CR</u>					
022033 001				>A> NDF	Feb 28, 2011
<u>FLUVOXAMINE MALEATE - LUVOX CR</u>					
022033 002				>A> NDF	Feb 28, 2011
<u>FOSAPREPITANT DIMEGLUMINE - EMEND</u>					
022023 001	>A> 5512570	Mar 04, 2014		U-850	
	>A> 5538982	Jul 23, 2013		U-850	
	>A> 5691336	Mar 04, 2014	DS DP		
	>A> 5716942	Feb 10, 2015		U-850	
	>A> 7214692	Sep 18, 2012		U-850	
<u>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</u>					
021700 004	>A> 5002953	Sep 17, 2011	DS DP U-840		
<u>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</u>					
021700 005	>A> 5002953	Sep 17, 2011	DS DP U-840		
<u>GRANISETRON HYDROCHLORIDE - GRANISETRON HYDROCHLORIDE</u>					
077177 001				>A> PC	Jun 28, 2008
<u>GRANISETRON HYDROCHLORIDE - GRANISETRON HYDROCHLORIDE PRESERVATIVE FREE</u>					
077165 001				>A> PC	Jun 28, 2008
<u>LAMIVUDINE - EPIVIR</u>					
020564 001	>A> 5047407	Nov 17, 2009	DS DP U-257		
<u>LEVOCETIRIZINE DIHYDROCHLORIDE - XYZAL</u>					
022157 001	>A> 5698558	Sep 24, 2012		U-852	
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>					
021977 004	>A> 7105486	Jun 29, 2023		U-842	
	>A> 7223735	Jun 29, 2023	DP		
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>					
021977 005	>A> 7105486	Jun 29, 2023		U-842	
	>A> 7223735	Jun 29, 2023	DP		

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<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>					
021977 006	>A> 7105486	Jun 29, 2023	U-842		
	>A> 7223735	Jun 29, 2023	DP		
<u>MENTHOL; METHYL SALICYLATE - SALONPAS</u>					
022029 001				>A> NDF >A> NC	Feb 20, 2011 Feb 20, 2011
<u>METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE - JANUMET</u>					
022044 001	>A> 7326708	Apr 11, 2026	DS DP	U-802	
<u>METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE - JANUMET</u>					
022044 002	>A> 7326708	Apr 11, 2026	DS DP	U-802	
<u>MICAFUNGIN SODIUM - MYCAMINE</u>					
021506 002	>A> 6107458	Sep 29, 2015	DS DP	U-845	>A> I-554 Jan 22, 2011
	>A> 6107458	Sep 29, 2015	DS DP	U-650	
	>A> 6265536	Sep 29, 2015	DS DP	U-845	
	>A> 6265536	Sep 29, 2015	DS DP	U-650	
	>A> 6774104	Jan 08, 2021	DP	U-845	
	>A> 6774104	Jan 08, 2021	DP	U-650	
<u>MICAFUNGIN SODIUM - MYCAMINE</u>					
021506 003	>A> 5376634	Dec 27, 2011	DS DP	>A> I-554 >A> NCE	Jan 22, 2011 Mar 16, 2010
	>A> 6107458	Sep 29, 2015	DS DP	U-845	
	>A> 6107458	Sep 29, 2015	DS DP	U-650	
	>A> 6265536	Sep 29, 2015	DS DP	U-845	
	>A> 6265536	Sep 29, 2015	DS DP	U-650	
	>A> 6774104	Jan 08, 2021	DP	U-845	
	>A> 6774104	Jan 08, 2021	DP	U-650	
<u>MODAFINIL - PROVIGIL</u>					
020717 001	>A> 7297346	Nov 29, 2023	DP		
<u>MODAFINIL - PROVIGIL</u>					
020717 002	>A> 7297346	Nov 29, 2023	DP		
<u>MOMETASONE FUROATE - ASMANEX TWISTHALER</u>					
021067 001				>A> NPP	Feb 01, 2011
<u>NEBIVOLOL HYDROCHLORIDE - BYSTOLIC</u>					
021742 002	>A> 5759580	Jun 02, 2015	DP	U-3	
	>A> 6545040	Apr 08, 2020	DP		
<u>NEBIVOLOL HYDROCHLORIDE - BYSTOLIC</u>					
021742 003	>A> 5759580	Jun 02, 2015	DP	U-3	
	>A> 6545040	Apr 08, 2020	DP		
<u>NEBIVOLOL HYDROCHLORIDE - BYSTOLIC</u>					
021742 004	>A> 5759580	Jun 02, 2015	DP	U-3	
	>A> 6545040	Apr 08, 2020	DP		
<u>NESIRITIDE RECOMBINANT - NATRECOR</u>					
020920 001	>A> 5114923	May 19, 2014	DS DP	U-855	
<u>NIACIN; SIMVASTATIN - SIMCOR</u>					
022078 001				>A> NC	Feb 15, 2011
<u>NIACIN; SIMVASTATIN - SIMCOR</u>					
022078 002				>A> NC	Feb 15, 2011
<u>NIACIN; SIMVASTATIN - SIMCOR</u>					
022078 003				>A> NC	Feb 15, 2011
<u>NISOLDIPINE - SULAR</u>					
020356 005	>A> 5422123	Jun 06, 2012	DP	DP	
	>A> 5626874	Nov 30, 2014	DP		
<u>NISOLDIPINE - SULAR</u>					
020356 006	>A> 5422123	Jun 06, 2012	DP	DP	
	>A> 5626874	Nov 30, 2014	DP		

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<u>NISOLDIPINE - SULAR</u>					
020356 007	>A> 5422123	Jun 06, 2012	DP		
	>A> 5626874	Nov 30, 2014	DP		
<u>NISOLDIPINE - SULAR</u>					
020356 008	>A> 5422123	Jun 06, 2012	DP		
	>A> 5626874	Nov 30, 2014	DP		
<u>OXCARBAZEPINE - OXCARBAZEPINE</u>					
078069 001				>A> PC	Apr 06, 2008
<u>OXCARBAZEPINE - OXCARBAZEPINE</u>					
078069 002				>A> PC	Apr 06, 2008
<u>OXCARBAZEPINE - OXCARBAZEPINE</u>					
078069 003				>A> PC	Apr 06, 2008
<u>PANTOPRAZOLE SODIUM - PANTOPRAZOLE SODIUM</u>					
077056 001				>A> PC	Jun 18, 2008
<u>PANTOPRAZOLE SODIUM - PANTOPRAZOLE SODIUM</u>					
077056 002				>A> PC	Jun 18, 2008
<u>PANTOPRAZOLE SODIUM - PANTOPRAZOLE SODIUM</u>					
077058 001				>A> PC	Jun 18, 2008
<u>PANTOPRAZOLE SODIUM - PANTOPRAZOLE SODIUM</u>					
077058 002				>A> PC	Jun 18, 2008
<u>PEMETREXED DISODIUM - ALIMTA</u>					
021462 002	>A> 5217974	Mar 29, 2011		U-551	
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>					
020667 007	>A> 4886812	Mar 25, 2011	DS DP	>A> I-517	Nov 07, 2009
	>A> 6001861	Jan 16, 2018		U-784	
	>A> 6194445	Jan 16, 2018		U-784	
<u>PREDNISOLONE ACETATE - FLO-PRED</u>					
022067 001	>A> 5881926	Mar 16, 2016	DP		
	>A> 6071523	Jun 03, 2018	DP		
	>A> 6102254	Mar 11, 2013	DP		
	>A> 6399079	Jun 03, 2018	DP		
	>A> 6656482	Jun 03, 2018	DP		
<u>PREDNISOLONE ACETATE - FLO-PRED</u>					
022067 002	>A> 5881926	Mar 16, 2016	DP		
	>A> 6071523	Jun 03, 2018	DP		
	>A> 6102254	Mar 11, 2013	DP		
	>A> 6399079	Jun 03, 2018	DP		
	>A> 6656482	Jun 03, 2018	DP		
<u>SEVELAMER CARBONATE - RENVELA</u>					
022127 001	>A> 5496545	Aug 11, 2013	DP	U-246	
	>A> 5667775	Sep 16, 2014		U-246	
	>A> 6509013	Aug 11, 2013	DP		
	>A> 6858203	Aug 11, 2013	DP	U-246	
	>A> 7014846	Aug 11, 2013	DP	U-246	
<u>SITAGLIPTIN PHOSPHATE - JANUVIA</u>					
021995 001	>A> 7326708	Apr 11, 2026	DS DP	U-802	
<u>SITAGLIPTIN PHOSPHATE - JANUVIA</u>					
021995 002	>A> 7326708	Apr 11, 2026	DS DP	U-802	
<u>SITAGLIPTIN PHOSPHATE - JANUVIA</u>					
021995 003	>A> 7326708	Apr 11, 2026	DS DP	U-802	
<u>SODIUM OXYBATE - XYREM</u>					
021196 001	>A> 6780889	Jul 04, 2020	DP		
	>A> 7262219	Jul 04, 2020	DP		
<u>SOMATROPIN RECOMBINANT - ACCRETROPIN</u>					
021538 001				>A> NP	Jan 23, 2011

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<u>SOMATROPIN RECOMBINANT - OMNITROPE</u>					
021426 003				>A> NP	May 30, 2009
<u>SUMATRIPTAN SUCCINATE - IMITREX STATDOSE</u>					
020080 002	>A> 5037845	Aug 06, 2008	DS DP U-848		
	>A> 5037845*PED	Feb 06, 2009			
<u>TADALAFIL - CIALIS</u>					
021368 001				>A> D-111	Jan 07, 2011
<u>TADALAFIL - CIALIS</u>					
021368 004	>A> 5859006	Nov 21, 2017	DS DP	>A> D-111	Jan 07, 2011
	>A> 6140329	Jul 11, 2016	DP U-155	>A> NCE	Nov 21, 2008
	>A> 6821975	Nov 19, 2020	DS DP U-614		
	>A> 6821975	Nov 19, 2020	DS DP U-533		
	>A> 6943166	Apr 26, 2020	U-155		
	>A> 7182958	Apr 26, 2020	DP U-155		
<u>TECHNETIUM TC-99M SESTAMIBI KIT - CARDIOLITE</u>					
019785 001	>A> 4988827	Jan 29, 2008			
	>A> 4988827*PED	Jul 29, 2008			
<u>TERBINAFINE - LAMISIL AT</u>					
021958 001	>A> 6121314	May 18, 2012		U-540	
	>A> 6121314	May 18, 2012		U-504	
<u>TESTOSTERONE - TESTIM</u>					
021454 001	>A> 7320968	Jan 18, 2025		U-843	
<u>TIGECYCLINE - TYGACIL</u>					
021821 001	>A> 5494903	Apr 09, 2016	DS DP		
<u>TIOTROPIUM BROMIDE MONOHYDRATE - SPIRIVA</u>					
021395 001	>A> 5478578	Dec 26, 2012	DP		
	>A> 7309707	Mar 10, 2023	DS DP		
<u>TRIAMCINOLONE ACETONIDE - TRIESENCE</u>					
022048 001	>A> 6395294	Jan 13, 2020	DP U-846		
<u>VALACYCLOVIR HYDROCHLORIDE - VALTREX</u>					
020487 001	>A> 4957924	Jun 23, 2009		U-530	
	>A> 4957924*PED	Dec 23, 2009			
	>A> 5879706	Jan 19, 2016		U-530	
	>A> 5879706*PED	Jul 19, 2016			
	>A> 6107302	Jan 19, 2016		U-530	
	>A> 6107302*PED	Jul 19, 2016			
<u>VALACYCLOVIR HYDROCHLORIDE - VALTREX</u>					
020487 002	>A> 4957924	Jun 23, 2009		U-530	
	>A> 4957924*PED	Dec 23, 2009			
	>A> 5879706	Jan 19, 2016		U-530	
	>A> 5879706*PED	Jul 19, 2016			
	>A> 6107302	Jan 19, 2016		U-530	
	>A> 6107302*PED	Jul 19, 2016			
<u>VALGANCICLOVIR HYDROCHLORIDE - VALCYTE</u>					
021304 001	>A> 6083953	Mar 29, 2015	DS DP U-854		
	>A> 6083953	Mar 29, 2015	DS DP U-384		

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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.

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**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>HYDROXYETHYL STARCH 130/0.4 IN 6% SODIUM CHLORIDE 0.9% - VOLUVEN</u> 070012 001				>A> 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, 28th 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>