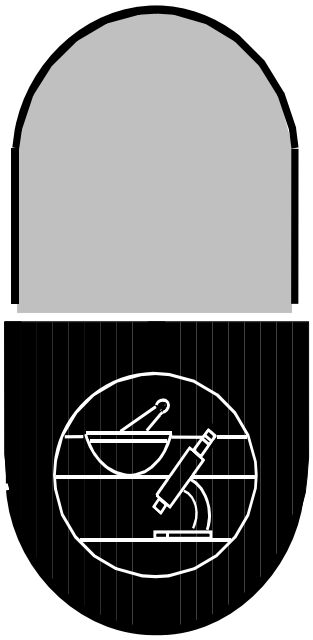
CUMULATIVE SUPPLEMENT 02
February 2008



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

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28th EDITION

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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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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.

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREVIATED NAME)
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

CATEGORIES COUNTED	DEC 2007	MAR 2007	JUN 2007	SEPT 2007
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

[1]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 proceeded 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.

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

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
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

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	DISC
>A>		@	50MG/5ML	N73115	001	Aug 23, 1991	Feb	DISC

AMIODARONE HYDROCHLORIDE

INJECTABLE; INJECTION
AMIODARONE HYDROCHLORIDE

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

TABLET; ORAL
AMIODARONE HYDROCHLORIDE

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

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

TABLET; ORAL
ATENOLOL

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

ATROPINE SULFATE; EDROPHONIUM CHLORIDE

INJECTABLE; INJECTION
ENLON-PLUS

>D>									
>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	

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; INJECTION						
		BLEOMYCIN 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 TARTRATE						
		SOLUTION/DROPS; OPHTHALMIC						
		BRIMONIDINE TARTRATE						
	AT	SANDOZ	0.2%	N78075	001	Jan 30, 2008	Jan	NEWA
>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
>D>		MYBANIL						
>D>		+ MORTON GROVE	12.5MG/5ML;10MG/5ML	N88626	001	Oct 12, 1984	Feb	DISC
		BUPROPION HYDROCHLORIDE						
		TABLET, EXTENDED RELEASE; ORAL						
		BUPROPION HYDROCHLORIDE						
>A>	AB1	ACTAVIS	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
		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						
>A>		CALCIUM ACETATE						
>A>	AB	ROXANE	EQ 169MG CALCIUM	N77728	001	Feb 26, 2008	Feb	NEWA
		PHOSLO GELCAPS						
>D>		+ FRESENIUS MEDCL	EQ 169MG CALCIUM	N21160	003	Apr 02, 2001	Feb	CFTG
>A>	AB	+	EQ 169MG CALCIUM	N21160	003	Apr 02, 2001	Feb	CFTG
		TABLET; ORAL						
		CALCIUM ACETATE						
		+ ROXANE	EQ 169MG CALCIUM	N77693	001	Jan 30, 2008	Jan	NEWA
		CAPTOPRIL						
		TABLET; ORAL						
		CAPTOPRIL						
>D>	AB	SANDOZ	12.5MG	N74481	001	Feb 13, 1996	Feb	DISC
>A>		@	12.5MG	N74481	001	Feb 13, 1996	Feb	DISC
>D>	AB		12.5MG	N74519	001	Feb 13, 1996	Feb	DISC
>A>		@	12.5MG	N74519	001	Feb 13, 1996	Feb	DISC
>D>	AB		25MG	N74481	002	Feb 13, 1996	Feb	DISC
>A>		@	25MG	N74481	002	Feb 13, 1996	Feb	DISC

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

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

CEFTRIAXONE SODIUM

INJECTABLE; IM-IV
CEFTRIAXONE

	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

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
ZYRTEC

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

CICLESONIDE

AEROSOL, METERED; INHALATION
ALVESCO

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

CIPROFLOXACIN HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
CIPROFLOXACIN HYDROCHLORIDE

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

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

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	+ MORTON GROVE	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
>A> COSYNTROPIN

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

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

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          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
>A>         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

DEXCHLORPHENIRAMINE MALEATE

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

DEXTROAMPHETAMINE SULFATE

SOLUTION; ORAL
DEXTROAMPHETAMINE SULFATE
+ OUTLOOK PHARMS 5MG/5ML N40776 001 Jan 29, 2008 Jan NEWA

DIAZEPAM

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

DICLOFENAC SODIUM

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

DICLOXACILLIN SODIUM

FOR SUSPENSION; ORAL
DICLOXACILLIN SODIUM
@ APOTHECON EQ 62.5MG BASE/5ML N61455 001 Jan DISC

DILTIAZEM HYDROCHLORIDE

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

DIPHENHYDRAMINE HYDROCHLORIDE

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
>D> ENLON

>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

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

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

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

FLUOXETINE HYDROCHLORIDE

CAPSULE; ORAL
FLUOXETINE

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

FLUTICASONE PROPIONATE

SPRAY, METERED; NASAL
FLUTICASONE PROPIONATE

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

FLUVOXAMINE MALEATE

CAPSULE, EXTENDED RELEASE; ORAL
LUVOX CR

>A>		SOLVAY	100MG	N22033	001	Feb 28, 2008	Feb	NEWA
>A>		+	150MG	N22033	002	Feb 28, 2008	Feb	NEWA

FOMEPIZOLE

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

FOSAPREPITANT DIMEGLUMINE

POWDER; INTRAVENOUS
EMEND

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

GLIPIZIDE; METFORMIN HYDROCHLORIDE

TABLET; ORAL
GLIPIZIDE AND METFORMIN HYDROCHLORIDE

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

GRANISETRON HYDROCHLORIDE

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	

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

HYDROXYCHLOROQUINE SULFATE

TABLET; ORAL
HYDROXYCHLOROQUINE SULFATE

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

HYDROXYUREA

TABLET; ORAL
HYDROXYUREA

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

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

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

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

TABLET; ORAL

LEVOXYL

	AB1, AB3	+	KING PHARMS	0.2MG	N21301	011	May 25, 2001	Jan	CRLD
		@		0.3MG	N21301	012	May 25, 2001	Jan	DISC

UNITHROID

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

LITHIUM CARBONATE

CAPSULE; ORAL

ESKALITH

	AB		NOVEN THERAP	300MG	N16860	001		Jan	CAHN

TABLET, EXTENDED RELEASE; ORAL

LITHOBID

	AB	+	NOVEN THERAP	300MG	N18027	001		Jan	CAHN

MELOXICAM

TABLET; ORAL

MELOXICAM

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

MEPROBAMATE

TABLET; ORAL

MEPROBAMATE

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

METAPROTERENOL SULFATE

SYRUP; ORAL

METAPROTERENOL SULFATE

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

METHSCOPOLAMINE BROMIDE

TABLET; ORAL

PAMINE

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

PAMINE FORTE

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

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	N18154	001		Jan	DISC
			@	10MG	N18154	003		Jan	DISC

MOMETASONE FUROATE

POWDER; INHALATION
ASMANEX TWISTHALER

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

MUPIROCIN

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

PACLITAXEL

INJECTABLE; INJECTION

PACLITAXEL

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

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

PHENYTOIN SODIUM

CAPSULE; ORAL

EXTENDED PHENYTOIN SODIUM

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

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
>A>		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

TABLET; ORAL
PRAVASTATIN SODIUM
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
\+ EQ 15MG BASE/5ML N22067 002 Jan 17, 2008 Jan NEWA

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION; ORAL
PREDNISOLONE SODIUM PHOSPHATE
>A> AA PHARM ASSOC EQ 10MG BASE/5ML N78465 001 Mar 07, 2008 Feb NEWA

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

PROMETHAZINE HYDROCHLORIDE

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

PROPRANOLOL HYDROCHLORIDE

INJECTABLE; INJECTION
PROPRANOLOL HYDROCHLORIDE
AP HIKMA FARMACEUTICA 1MG/ML N77760 001 Jan 31, 2008 Jan NEWA

SERTACONAZOLE NITRATE

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

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

>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	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

ZIDOVUDINE

TABLET; ORAL

ZIDOVUDINE

	AB	MATRIX LABS LTD	300MG	N78922	001	Feb 14, 2008	Jan	NEWA

ZILEUTON

TABLET; ORAL

>D>		ZYFLO							
>D>	+	CRITICAL	600MG	N20471	003	Dec 09, 1996	Feb	DISC
>A>		@	600MG	N20471	003	Dec 09, 1996	Feb	DISC

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

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

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATON DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
ADEFOVIR DIPIVOXIL - HEPSERA					
021449 001				**>A>** NPP	Dec 19, 2010
ALENDRONATE SODIUM - ALENDRONATE SODIUM					
075710 003				**>A>** PC	Aug 04, 2008
ALENDRONATE SODIUM - ALENDRONATE SODIUM					
076184 001				**>A>** PC	Aug 04, 2008
ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE - TEKTURNA HCT					
022107 001				**>A>** NCE	Mar 05, 2012
				>A> NC	Jan 18, 2011
ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE - TEKTURNA HCT					
022107 002				**>A>** NCE	Mar 05, 2012
				>A> NC	Jan 18, 2011
ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE - TEKTURNA HCT					
022107 003				**>A>** NCE	Mar 05, 2012
				>A> NC	Jan 18, 2011
ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE - TEKTURNA HCT					
022107 004				**>A>** NCE	Mar 05, 2012
				>A> NC	Jan 18, 2011
APREPITANT - EMEND					
021549 001	**>A>** 5719147	Apr 17, 2015	DS DP U-853		
	>A> 7214692	Sep 18, 2012	U-853		
APREPITANT - EMEND					
021549 002	**>A>** 7214692	Sep 18, 2012	U-853		
APREPITANT - EMEND					
021549 003	**>A>** 7214692	Sep 18, 2012	U-853		
ARFORMOTEROL TARTRATE - BROVANA					
021912 001	**>A>** 6040344	Nov 12, 2016	DS		
	>A> 6472563	Nov 09, 2021	DS		
	>A> 6720453	Nov 09, 2021	DS		
	>A> 7145036	Nov 09, 2021	DS		
ARIPIPRAZOLE - ABILIFY					
021436 001				**>A>** D-110	Oct 29, 2010
				>A> I-555	Feb 27, 2011
				>A> PED	Aug 27, 2011
				>A> PED	Apr 29, 2011
ARIPIPRAZOLE - ABILIFY					
021436 002				**>A>** D-110	Oct 29, 2010
				>A> I-555	Feb 27, 2011
				>A> PED	Aug 27, 2011
				>A> PED	Apr 29, 2011
ARIPIPRAZOLE - ABILIFY					
021436 003				**>A>** D-110	Oct 29, 2010
				>A> I-555	Feb 27, 2011
				>A> PED	Aug 27, 2011
				>A> PED	Apr 29, 2011
ARIPIPRAZOLE - ABILIFY					
021436 004				**>A>** D-110	Oct 29, 2010
				>A> I-555	Feb 27, 2011
				>A> PED	Aug 27, 2011
				>A> PED	Apr 29, 2011
ARIPIPRAZOLE - ABILIFY					
021436 005				**>A>** D-110	Oct 29, 2010
				>A> I-555	Feb 27, 2011
				>A> PED	Aug 27, 2011
				>A> PED	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 EXPIRATON DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
ARIPIPRAZOLE - ABILIFY					
021436 006				>A> D-110	Oct 29, 2010
				>A> I-555	Feb 27, 2011
				>A> PED	Aug 27, 2011
				>A> PED	Apr 29, 2011
ARIPIPRAZOLE - ABILIFY					
021713 001				>A> D-110	Oct 29, 2010
				>A> I-555	Feb 27, 2011
				>A> PED	Aug 27, 2011
				>A> PED	Apr 29, 2011
ARIPIPRAZOLE - ABILIFY					
021729 002				>A> D-110	Oct 29, 2010
				>A> I-555	Feb 27, 2011
				>A> PED	Aug 27, 2011
				>A> PED	Apr 29, 2011
ARIPIPRAZOLE - ABILIFY					
021729 003				>A> D-110	Oct 29, 2010
				>A> I-555	Feb 27, 2011
				>A> PED	Aug 27, 2011
				>A> PED	Apr 29, 2011
ARIPIPRAZOLE - ABILIFY					
021729 004				>A> D-110	Oct 29, 2010
				>A> I-555	Feb 27, 2011
				>A> PED	Aug 27, 2011
				>A> PED	Apr 29, 2011
ARIPIPRAZOLE - ABILIFY					
021729 005				>A> D-110	Oct 29, 2010
				>A> I-555	Feb 27, 2011
				>A> PED	Aug 27, 2011
				>A> PED	Apr 29, 2011
ARIPIPRAZOLE - ABILIFY					
021866 001				>A> D-110	Oct 29, 2010
				>A> I-555	Feb 27, 2011
				>A> PED	Aug 27, 2011
				>A> PED	Apr 29, 2011
BRIMONIDINE TARTRATE; TIMOLOL MALEATE - COMBIGAN					
021398 001	>A> 7030149	Apr 19, 2022	U-849		
	>A> 7030976	Apr 19, 2022	U-849		
	>A> 7323463	Jan 19, 2023	DP		
CARVEDILOL - COREG					
020297 001	>A> RE40000	Jun 07, 2015	U-233		
	>A> RE40000*PED	Dec 07, 2015			
CARVEDILOL - COREG					
020297 002	>A> RE40000	Jun 07, 2015	U-233		
	>A> RE40000*PED	Dec 07, 2015			
CARVEDILOL - COREG					
020297 003	>A> RE40000	Jun 07, 2015	U-233		
	>A> RE40000*PED	Dec 07, 2015			
CARVEDILOL - COREG					
020297 004	>A> RE40000	Jun 07, 2015	U-233		
	>A> RE40000*PED	Dec 07, 2015			
CARVEDILOL PHOSPHATE - COREG CR					
022012 001	>A> RE40000	Jun 07, 2015	U-777		
	>A> RE40000*PED	Dec 07, 2015			
CARVEDILOL PHOSPHATE - COREG CR					
022012 002	>A> RE40000	Jun 07, 2015	U-777		
	>A> RE40000*PED	Dec 07, 2015			

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

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATON DATE		PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
CARVEDILOL PHOSPHATE - COREG CR						
022012 003	**>A>** RE40000	Jun 07, 2015		U-777		
	>A> RE40000*PED	Dec 07, 2015				
CARVEDILOL PHOSPHATE - COREG CR						
022012 004	**>A>** RE40000	Jun 07, 2015		U-777		
	>A> RE40000*PED	Dec 07, 2015				
CICLESONIDE - ALVESCO						
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		
CICLESONIDE - ALVESCO						
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		
CLOFARABINE - CLOLAR						
021673 001	**>A>** 5661136	Jan 14, 2018		U-626		
COLESEVELAM HYDROCHLORIDE - WELCHOL						
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		
DAPTOMYCIN - CUBICIN						
021572 002	**>A>** RE39071	Jun 15, 2016	DS	DP U-728		
DARIFENACIN HYDROBROMIDE - ENABLEX						
021513 001	**>A>** 5096890	Mar 13, 2015	DS	DP U-631		

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

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATON DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
DARIFENACIN HYDROBROMIDE - ENABLEX					
021513 002	**>A>** 5096890	Mar 13, 2015	DS DP U-631		
DARUNAVIR ETHANOLATE - PREZISTA					
021976 002				**>A>** NCE	Jun 23, 2011
DEXTROAMPHETAMINE SULFATE - DEXTROAMPHETAMINE SULFATE					
076814 001				**>A>** PC	Aug 04, 2008
ELETRIPTAN HYDROBROMIDE - RELPAX					
021016 001	**>A>** 6110940	Aug 29, 2017			
ELETRIPTAN HYDROBROMIDE - RELPAX					
021016 002	**>A>** 6110940	Aug 29, 2017			
ENTECAVIR - BARACLUDE					
021797 001	**>A>** 5206244	Feb 21, 2015	DS		
ENTECAVIR - BARACLUDE					
021797 002	**>A>** 5206244	Feb 21, 2015	DS		
ENTECAVIR - BARACLUDE					
021798 001	**>A>** 5206244	Feb 21, 2015	DS		
EPLERENONE - INSPRA					
021437 001				**>A>** M-72	Jan 31, 2011
				>A> PED	Jul 31, 2011
EPLERENONE - INSPRA					
021437 002				**>A>** M-72	Jan 31, 2011
				>A> PED	Jul 31, 2011
ESTRADIOL; NORGESTIMATE - PREFEST					
021040 001	**>A>** 7320970	Mar 30, 2020	DP U-844		
ETHINYL ESTRADIOL; LEVONORGESTREL - SEASONIQUE					
021840 001	**>A>** 7320969	Jan 30, 2024	U-828		
ETRAVIRINE - INTELENCE					
022187 001				**>A>** NCE	Jan 18, 2013
EXENATIDE SYNTHETIC - BYETTA					
021773 001	**>A>** 5424286	Dec 01, 2016	U-653		
EZETIMIBE - ZETIA					
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			
EZETIMIBE; SIMVASTATIN - VYTORIN					
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			
EZETIMIBE; SIMVASTATIN - VYTORIN					
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			
EZETIMIBE; SIMVASTATIN - VYTORIN					
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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EZETIMIBE; SIMVASTATIN - VYTORIN							
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					
FENOFIBRATE - TRICOR							
021656 001	**>A>** 7320802	Feb 21, 2023			U-847		
FENOFIBRATE - TRICOR							
021656 002	**>A>** 7320802	Feb 21, 2023			U-847		
FENTANYL CITRATE - FENTORA							
021947 006	**>A>** 6200604	Mar 26, 2019			U-767		
	>A> 6974590	Mar 26, 2019			U-767		
FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 100/50							
021077 001	**>A>** RE40045	Sep 07, 2010		DP			
FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 250/50							
021077 002	**>A>** RE40045	Sep 07, 2010		DP			
FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 500/50							
021077 003	**>A>** RE40045	Sep 07, 2010		DP			
FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR HFA							
021254 001	**>A>** RE40045	Sep 07, 2010		DP			
FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR HFA							
021254 002	**>A>** RE40045	Sep 07, 2010		DP			
FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR HFA							
021254 003	**>A>** RE40045	Sep 07, 2010		DP			
FLUVOXAMINE MALEATE - LUVOX CR							
022033 001						**>A>** NDF	Feb 28, 2011
FLUVOXAMINE MALEATE - LUVOX CR							
022033 002						**>A>** NDF	Feb 28, 2011
FOSAPREPITANT DIMEGLUMINE - EMEND							
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		
GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL							
021700 004	**>A>** 5002953	Sep 17, 2011	DS	DP	U-840		
GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL							
021700 005	**>A>** 5002953	Sep 17, 2011	DS	DP	U-840		
GRANISETRON HYDROCHLORIDE - GRANISETRON HYDROCHLORIDE							
077177 001						**>A>** PC	Jun 28, 2008
GRANISETRON HYDROCHLORIDE - GRANISETRON HYDROCHLORIDE PRESERVATIVE FREE							
077165 001						**>A>** PC	Jun 28, 2008
LAMIVUDINE - EPIVIR							
020564 001	**>A>** 5047407	Nov 17, 2009	DS	DP	U-257		
LEVOCETIRIZINE DIHYDROCHLORIDE - XYZAL							
022157 001	**>A>** 5698558	Sep 24, 2012			U-852		
LISDEXAMFETAMINE DIMESYLATE - VYVANSE							
021977 004	**>A>** 7105486	Jun 29, 2023			U-842		
	>A> 7223735	Jun 29, 2023		DP			
LISDEXAMFETAMINE DIMESYLATE - VYVANSE							
021977 005	**>A>** 7105486	Jun 29, 2023			U-842		
	>A> 7223735	Jun 29, 2023		DP			

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

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NISOLDIPINE - SULAR							
020356 007	**>A>** 5422123	Jun 06, 2012		DP			
	>A> 5626874	Nov 30, 2014		DP			
NISOLDIPINE - SULAR							
020356 008	**>A>** 5422123	Jun 06, 2012		DP			
	>A> 5626874	Nov 30, 2014		DP			
OXCARBAZEPINE - OXCARBAZEPINE							
078069 001						**>A>** PC	Apr 06, 2008
OXCARBAZEPINE - OXCARBAZEPINE							
078069 002						**>A>** PC	Apr 06, 2008
OXCARBAZEPINE - OXCARBAZEPINE							
078069 003						**>A>** PC	Apr 06, 2008
PANTOPRAZOLE SODIUM - PANTOPRAZOLE SODIUM							
077056 001						**>A>** PC	Jun 18, 2008
PANTOPRAZOLE SODIUM - PANTOPRAZOLE SODIUM							
077056 002						**>A>** PC	Jun 18, 2008
PANTOPRAZOLE SODIUM - PANTOPRAZOLE SODIUM							
077058 001						**>A>** PC	Jun 18, 2008
PANTOPRAZOLE SODIUM - PANTOPRAZOLE SODIUM							
077058 002						**>A>** PC	Jun 18, 2008
PEMETREXED DISODIUM - ALIMTA							
021462 002	**>A>** 5217974	Mar 29, 2011			U-551		
PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX							
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		
PREDNISOLONE ACETATE - FLO-PRED							
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			
PREDNISOLONE ACETATE - FLO-PRED							
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			
SEVELAMER CARBONATE - RENVELA							
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		
SITAGLIPTIN PHOSPHATE - JANUVIA							
021995 001	**>A>** 7326708	Apr 11, 2026	DS	DP	U-802		
SITAGLIPTIN PHOSPHATE - JANUVIA							
021995 002	**>A>** 7326708	Apr 11, 2026	DS	DP	U-802		
SITAGLIPTIN PHOSPHATE - JANUVIA							
021995 003	**>A>** 7326708	Apr 11, 2026	DS	DP	U-802		
SODIUM OXYBATE - XYREM							
021196 001	**>A>** 6780889	Jul 04, 2020		DP			
	>A> 7262219	Jul 04, 2020		DP			
SOMATROPIN RECOMBINANT - ACCRETROPIN							
021538 001						**>A>** NP	Jan 23, 2011

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SOMATROPIN RECOMBINANT - OMNITROPE							
021426 003						**>A>** NP	May 30, 2009
SUMATRIPTAN SUCCINATE - IMITREX STATDOSE							
020080 002	**>A>** 5037845	Aug 06, 2008	DS	DP	U-848		
	>A> 5037845*PED	Feb 06, 2009					
TADALAFIL - CIALIS							
021368 001						**>A>** D-111	Jan 07, 2011
TADALAFIL - CIALIS							
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		
TECHNETIUM TC-99M SESTAMIBI KIT - CARDIOLITE							
019785 001	**>A>** 4988827	Jan 29, 2008					
	>A> 4988827*PED	Jul 29, 2008					
TERBINAFINE - LAMISIL AT							
021958 001	**>A>** 6121314	May 18, 2012			U-540		
	>A> 6121314	May 18, 2012			U-504		
TESTOSTERONE - TESTIM							
021454 001	**>A>** 7320968	Jan 18, 2025			U-843		
TIGECYCLINE - TYGACIL							
021821 001	**>A>** 5494903	Apr 09, 2016	DS	DP			
TIOTROPIUM BROMIDE MONOHYDRATE - SPIRIVA							
021395 001	**>A>** 5478578	Dec 26, 2012		DP			
	>A> 7309707	Mar 10, 2023	DS	DP			
TRIAMCINOLONE ACETONIDE - TRIESENCE							
022048 001	**>A>** 6395294	Jan 13, 2020		DP	U-846		
VALACYCLOVIR HYDROCHLORIDE - VALTREX							
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					
VALACYCLOVIR HYDROCHLORIDE - VALTREX							
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					
VALGANCICLOVIR HYDROCHLORIDE - VALCYTE							
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.

**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 EXPIRATON DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
HYDROXYETHYL STARCH 130/0.4 IN 6% SODIUM CHLORIDE 0.9% - VOLUVEN					
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