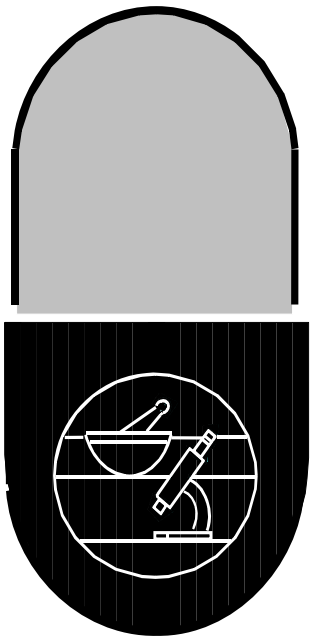
APPROVED DRUG PRODUCTS
With Therapeutic Equivalence Evaluations

The "Orange Book"

FDA data supplied by DrugPatentWatch.com

CUMULATIVE SUPPLEMENT 01
January 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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THERAPEUTIC EQUIVALENCE EVALUATIONS

28th EDITION

Cumulative Supplement 01

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CUMULATIVE SUPPLEMENT 01
December 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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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.

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREVIATED NAME)
None	

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.

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL
PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

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

ACETOHEXAMIDE

TABLET; ORAL
ACETOHEXAMIDE

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

ALENDRONATE SODIUM

TABLET; ORAL
ALENDRONATE SODIUM

>A>	AB		BARR	EQ 70MG BASE	N76184	001	Feb 06, 2008	Jan	NEWA
>A>	AB		TEVA PHARMS	EQ 5MG BASE	N75710	001	Feb 06, 2008	Jan	NEWA
>A>	AB			EQ 10MG BASE	N75710	002	Feb 06, 2008	Jan	NEWA
>A>	AB			EQ 35MG BASE	N75710	003	Feb 06, 2008	Jan	NEWA
>A>	AB			EQ 40MG BASE	N75710	004	Feb 06, 2008	Jan	NEWA
>A>	AB			EQ 70MG BASE	N75710	005	Feb 06, 2008	Jan	NEWA

FOSAMAX

>D>			MERCK	EQ 5MG BASE	N20560	003	Apr 25, 1997	Jan	CFTG
>D>				EQ 10MG BASE	N20560	001	Sep 29, 1995	Jan	CFTG
>D>				EQ 35MG BASE	N20560	004	Oct 20, 2000	Jan	CFTG
>D>				EQ 40MG BASE	N20560	002	Sep 29, 1995	Jan	CFTG
>D>		+		EQ 70MG BASE	N20560	005	Oct 20, 2000	Jan	CFTG
>A>	AB		MERCK AND CO INC	EQ 5MG BASE	N20560	003	Apr 25, 1997	Jan	CFTG
>A>	AB			EQ 10MG BASE	N20560	001	Sep 29, 1995	Jan	CFTG
>A>	AB			EQ 35MG BASE	N20560	004	Oct 20, 2000	Jan	CFTG
>A>	AB			EQ 40MG BASE	N20560	002	Sep 29, 1995	Jan	CFTG
>A>	AB	+		EQ 70MG BASE	N20560	005	Oct 20, 2000	Jan	CFTG

>A> ALISKIREN HEMIFUMARATE; HYDROCHLOROTHIAZIDE

>A> TABLET; ORAL
>A> TEKTURNA HCT

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

AMLODIPINE BESYLATE

TABLET; ORAL
AMLODIPINE BESYLATE

>A>	AB		INTERPHARM	EQ 2.5MG BASE	N78477	001	Jan 16, 2008	Jan	NEWA
>A>	AB			EQ 5MG BASE	N78477	002	Jan 16, 2008	Jan	NEWA
>A>	AB			EQ 10MG BASE	N78477	003	Jan 16, 2008	Jan	NEWA
>A>	AB		MUTUAL PHARMA	EQ 2.5MG BASE	N78081	001	Jan 31, 2008	Jan	NEWA
>A>	AB			EQ 5MG BASE	N78081	002	Jan 31, 2008	Jan	NEWA
>A>	AB			EQ 10MG BASE	N78081	003	Jan 31, 2008	Jan	NEWA

AMOXICILLIN

TABLET, EXTENDED RELEASE; ORAL

MOXATAG

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

AZITHROMYCIN

TABLET; ORAL

AZITHROMYCIN

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

AZTREONAM

INJECTABLE; INJECTION

AZACTAM

>D>		+	BRISTOL MYERS SQUIBB	500MG/VIAL	N50580	001	Dec 31, 1986	Jan	DISC
>A>		@		500MG/VIAL	N50580	001	Dec 31, 1986	Jan	DISC

BENZONATATE

CAPSULE; ORAL

BENZONATATE

>D>	AA		AMNEAL PHARM	100MG	N40682	001	Jul 30, 2007	Jan	CAHN
>D>	AA			200MG	N40682	002	Jul 30, 2007	Jan	CAHN
>A>	AA		ORIT LABS LLC	100MG	N40682	001	Jul 30, 2007	Jan	CAHN
>A>	AA			200MG	N40682	002	Jul 30, 2007	Jan	CAHN

BENZTROPINE MESYLATE

TABLET; ORAL

BENZTROPINE MESYLATE

>A>	AA		ACTAVIS TOTOWA	0.5MG	N40699	001	Feb 14, 2008	Jan	NEWA
>A>	AA			1MG	N40705	001	Feb 14, 2008	Jan	NEWA
>A>	AA			2MG	N40706	001	Feb 14, 2008	Jan	NEWA

BLEOMYCIN SULFATE

INJECTABLE; INJECTION

BLEOMYCIN

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

BLEOMYCIN SULFATE

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

BRIMONIDINE TARTRATE

SOLUTION/DROPS; OPHTHALMIC
BRIMONIDINE TARTRATE

>A>	AT	SANDOZ	0.2%	N78075	001	Jan 30, 2008	Jan	NEWA

CAFFEINE CITRATE

SOLUTION; ORAL
CAFFEINE CITRATE

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

CALCITRIOL

INJECTABLE; INJECTION
CALCITRIOL

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

CALCIUM ACETATE

>A>		TABLET; ORAL						
>A>		CALCIUM ACETATE						
>A>	+	ROXANE	EQ 169MG CALCIUM	N77693	001	Jan 30, 2008	Jan	NEWA

CEFADROXIL/CEFADROXIL HEMIHYDRATE

CAPSULE; ORAL
CEFADROXIL

>A>	AB	HIKMA	EQ 500MG BASE	N65311	001	Feb 07, 2006	Jan	CAHN
>D>	AB	WESTWARD	EQ 500MG BASE	N65311	001	Feb 07, 2006	Jan	CAHN

CEFTRIAXONE SODIUM

INJECTABLE; IM-IV
CEFTRIAXONE

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

CEFUROXIME AXETIL

FOR SUSPENSION; ORAL
CEFTIN

>D>		GLAXOSMITHKLINE	EQ 125MG BASE/5ML	N50672	001	Jun 30, 1994	Jan	CFTG
>A>	AB		EQ 125MG BASE/5ML	N50672	001	Jun 30, 1994	Jan	CFTG
>D>	+		EQ 250MG BASE/5ML	N50672	002	Apr 29, 1997	Jan	CFTG
>A>	AB +		EQ 250MG BASE/5ML	N50672	002	Apr 29, 1997	Jan	CFTG
>A>		CEFUROXIME AXETIL						
>A>	AB	RANBAXY	EQ 125MG BASE/5ML	N65323	001	Feb 05, 2008	Jan	NEWA
>A>	AB		EQ 250MG BASE/5ML	N65323	002	Feb 05, 2008	Jan	NEWA

TABLET; ORAL
CEFUROXIME AXETIL

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

CETIRIZINE HYDROCHLORIDE

SYRUP; ORAL
ZYRTEC

>A>		+	MCNEIL CONSUMER	5MG/5ML	N20346	001	Sep 27, 1996	Jan	CAHN
>D>		+	PFIZER	5MG/5ML	N20346	001	Sep 27, 1996	Jan	CAHN

CICLESONIDE

>A>			AEROSOL, METERED; INHALATION						
>A>			ALVESCO						
>A>			NYCOMED US	0.08MG/INH	N21658	002	Jan 10, 2008	Jan	NEWA
>A>		+		0.16MG/INH	N21658	003	Jan 10, 2008	Jan	NEWA

CIPROFLOXACIN HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
CIPROFLOXACIN HYDROCHLORIDE

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

CLOPIDOGREL BISULFATE

TABLET; ORAL
CLOPIDOGREL BISULFATE

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

CYCLOPHOSPHAMIDE

INJECTABLE; INJECTION
CYCLOPHOSPHAMIDE

>D>	AP		BAXTER HLTHCARE	100MG/VIAL	N88371	001	Jul 03, 1986	Jan	DISC
>A>			@	100MG/VIAL	N88371	001	Jul 03, 1986	Jan	DISC
>D>	AP			200MG/VIAL	N88372	001	Jul 03, 1986	Jan	DISC
>A>			@	200MG/VIAL	N88372	001	Jul 03, 1986	Jan	DISC
>D>	AP			500MG/VIAL	N88373	001	Jul 03, 1986	Jan	DISC
>A>			@	500MG/VIAL	N88373	001	Jul 03, 1986	Jan	DISC
>D>	AP			1GM/VIAL	N88374	001	Sep 24, 1986	Jan	DISC
>A>			@	1GM/VIAL	N88374	001	Sep 24, 1986	Jan	DISC
			LYOPHILIZED CYTOXAN						
>D>	AP	+	BRISTOL MYERS SQUIBB	100MG/VIAL	N12142	006	Dec 05, 1985	Jan	CTEC
>A>		+		100MG/VIAL	N12142	006	Dec 05, 1985	Jan	CTEC
>D>	AP	+		200MG/VIAL	N12142	007	Dec 10, 1985	Jan	CTEC
>A>		+		200MG/VIAL	N12142	007	Dec 10, 1985	Jan	CTEC
>D>	AP	+		500MG/VIAL	N12142	008	Jan 04, 1984	Jan	CTEC
>A>		+		500MG/VIAL	N12142	008	Jan 04, 1984	Jan	CTEC
>D>	AP	+		1GM/VIAL	N12142	010	Sep 24, 1985	Jan	CTEC
>A>		+		1GM/VIAL	N12142	010	Sep 24, 1985	Jan	CTEC
>D>	AP	+		2GM/VIAL	N12142	009	Dec 10, 1984	Jan	CTEC
>A>		+		2GM/VIAL	N12142	009	Dec 10, 1984	Jan	CTEC
>D>			NEOSAR						
>D>	AP		TEVA PARENTERAL	100MG/VIAL	N87442	001	Feb 16, 1982	Jan	DISC
>A>			@	100MG/VIAL	N87442	001	Feb 16, 1982	Jan	DISC
>D>	AP			200MG/VIAL	N87442	002	Feb 16, 1982	Jan	DISC
>A>			@	200MG/VIAL	N87442	002	Feb 16, 1982	Jan	DISC
>D>	AP			500MG/VIAL	N87442	003	Feb 16, 1982	Jan	DISC
>A>			@	500MG/VIAL	N87442	003	Feb 16, 1982	Jan	DISC
>D>	AP			1GM/VIAL	N87442	004	Jul 08, 1983	Jan	DISC
>A>			@	1GM/VIAL	N87442	004	Jul 08, 1983	Jan	DISC
>D>	AP			2GM/VIAL	N87442	005	Mar 30, 1989	Jan	DISC

		INJECTABLE; INJECTION							
>D>		NEOSAR							
>A>		@ TEVA PARENTERAL	2GM/VIAL	N87442	005	Mar 30, 1989	Jan	DISC	
		TABLET; ORAL							
		CYCLOPHOSPHAMIDE							
>D>	AB	ROXANE	25MG	N40032	001	Aug 17, 1999	Jan	CTEC	
>A>			25MG	N40032	001	Aug 17, 1999	Jan	CTEC	
>D>	AB		50MG	N40032	002	Aug 17, 1999	Jan	CRLD	
>A>		+	50MG	N40032	002	Aug 17, 1999	Jan	CRLD	
>D>		CYTOXAN							
>D>	AB	BRISTOL MYERS SQUIBB	25MG	N12141	002		Jan	DISC	
>A>		@	25MG	N12141	002		Jan	DISC	
>D>	AB	+	50MG	N12141	001		Jan	DISC	
>A>		@	50MG	N12141	001		Jan	DISC	
		DEXTROAMPHETAMINE SULFATE							
>A>		SOLUTION; ORAL							
>A>		DEXTROAMPHETAMINE SULFATE							
>A>		+ OUTLOOK PHARMS	5MG/5ML	N40776	001	Jan 29, 2008	Jan	NEWA	
		DICLOFENAC SODIUM							
		SOLUTION/DROPS; OPHTHALMIC							
		DICLOFENAC SODIUM							
>A>	AT	ALCON	0.1%	N78031	001	Feb 06, 2008	Jan	NEWA	
		DICLOXACILLIN SODIUM							
>D>		FOR SUSPENSION; ORAL							
>D>		DICLOXACILLIN SODIUM							
>D>		+ APOTHECON	EQ 62.5MG BASE/5ML	N61455	001		Jan	DISC	
>A>		@	EQ 62.5MG BASE/5ML	N61455	001		Jan	DISC	
		DIPYRIDAMOLE							
		TABLET; ORAL							
		DIPYRIDAMOLE							
>A>	AB	ZYDUS PHARMS USA INC	25MG	N40874	001	Jan 28, 2008	Jan	NEWA	
>A>	AB		50MG	N40874	002	Jan 28, 2008	Jan	NEWA	
>A>	AB		75MG	N40874	003	Jan 28, 2008	Jan	NEWA	
		EDETATE DISODIUM							
		INJECTABLE; INJECTION							
		EDETATE DISODIUM							
>D>	AP	APOTEX INC	150MG/ML	N40376	001	Nov 04, 2002	Jan	DISC	
>A>		@	150MG/ML	N40376	001	Nov 04, 2002	Jan	DISC	
		ESTRADIOL							
		GEL, METERED; TRANSDERMAL							
		ELESTRIN							
>D>	BX	+ BRADLEY PHARMS	0.06% (0.87GM/ACTIVATION)	N21813	001	Dec 15, 2006	Jan	CTEC	
>A>		+	0.06% (0.87GM/ACTIVATION)	N21813	001	Dec 15, 2006	Jan	CTEC	
		ESTROGEL							
>D>	BX	+ ASCEND	0.06% (1.25GM/ACTIVATION)	N21166	002	Feb 09, 2004	Jan	CTEC	
>A>		+	0.06% (1.25GM/ACTIVATION)	N21166	002	Feb 09, 2004	Jan	CTEC	

ETHAMBUTOL HYDROCHLORIDE

TABLET; ORAL
MYAMBUTOL

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

>A> ETRAVIRINE

>A> TABLET; ORAL
>A> INTELENCE

>A>	+	TIBOTEC	100MG	N22187	001	Jan 18, 2008	Jan	NEWA

FLUOXETINE HYDROCHLORIDE

CAPSULE; ORAL
FLUOXETINE

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

FLUTICASONE PROPIONATE

SPRAY, METERED; NASAL
FLUTICASONE PROPIONATE

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

>A> FOSAPREPITANT DIMEGLUMINE

>A> POWDER; INTRAVENOUS
>A> EMEND

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

GABAPENTIN

CAPSULE; ORAL
GABAPENTIN

>A>	AB	AUROBINDO PHARM	100MG	N78787	001	Jan 31, 2008	Jan	NEWA
>A>	AB		300MG	N78787	002	Jan 31, 2008	Jan	NEWA
>A>	AB		400MG	N78787	003	Jan 31, 2008	Jan	NEWA

GLIPIZIDE; METFORMIN HYDROCHLORIDE

TABLET; ORAL
GLIPIZIDE AND METFORMIN HYDROCHLORIDE

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

GRANISETRON HYDROCHLORIDE

TABLET; ORAL
GRANISETRON HYDROCHLORIDE

>A>	AB	MYLAN	EQ 1MG BASE	N78725	001	Jan 30, 2008	Jan	NEWA
>A>	AB	ORCHID HLTHCARE	EQ 1MG BASE	N78678	001	Feb 13, 2008	Jan	NEWA

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN SODIUM PRESERVATIVE FREE

>D>	AP	+ HOSPIRA	2,500 UNITS/ML	N05264	014	Apr 07, 1986	Jan	CTEC
>A>		+	2,500 UNITS/ML	N05264	014	Apr 07, 1986	Jan	CTEC

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE

SYRUP; ORAL
HYDROCODONE BITARTRATE AND HOMATROPINE METHYLBROMIDE

>A>	AA	HI TECH PHARMA	1.5MG/5ML;5MG/5ML	N40613	001	Feb 08, 2008	Jan	NEWA

HYDROCHLOROTHIAZIDE

CAPSULE; ORAL
HYDROCHLOROTHIAZIDE

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

HYDROXYCHLOROQUINE SULFATE

TABLET; ORAL
HYDROXYCHLOROQUINE SULFATE

>D>		@ IPCA	200MG	N40766	001	Jun 14, 2007	Jan	CMFD
>A>	AB	IPCA LABS LTD	200MG	N40766	001	Jun 14, 2007	Jan	CMFD

HYDROXYUREA

TABLET; ORAL
HYDROXYUREA

>D>		+ BARR	1GM	N75734	001	Aug 29, 2000	Jan	DISC
>A>		@	1GM	N75734	001	Aug 29, 2000	Jan	DISC

IMIPRAMINE PAMOATE

CAPSULE; ORAL
TOFRANIL-PM

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

INDOMETHACIN

CAPSULE; ORAL
INDOMETHACIN

>D>		@ IVAX PHARMS	25MG	N70719	001	Feb 12, 1986	Jan	CMFD
>A>	AB		25MG	N70719	001	Feb 12, 1986	Jan	CMFD
>D>		@	50MG	N70756	001	Feb 12, 1986	Jan	CMFD
>A>	AB		50MG	N70756	001	Feb 12, 1986	Jan	CMFD

ISOSORBIDE DINITRATE

TABLET; SUBLINGUAL
ISOSORBIDE DINITRATE

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

TABLET; SUBLINGUAL
ISOSORBIDE DINITRATE

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

KETOROLAC TROMETHAMINE

INJECTABLE; INJECTION
KETOROLAC TROMETHAMINE

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

LEVOCETIRIZINE DIHYDROCHLORIDE

>A>			SOLUTION; ORAL						
>A>			XYZAL						
>A>		+	UCB INC	2.5MG/5ML	N22157	001	Jan 28, 2008	Jan	NEWA

LEVONORDEFRIN; MEPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION
POLOCAINE W/ LEVONORDEFRIN

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

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

LITHIUM CARBONATE

CAPSULE; ORAL
ESKALITH

>D>	AB		JDS PHARMS	300MG	N16860	001		Jan	CAHN
>A>	AB		NOVEN THERAP	300MG	N16860	001		Jan	CAHN

TABLET, EXTENDED RELEASE; ORAL
LITHOBID

>D>	AB	+	JDS PHARMS	300MG	N18027	001		Jan	CAHN
>A>	AB	+	NOVEN THERAP	300MG	N18027	001		Jan	CAHN

MINOXIDIL

TABLET; ORAL

>D>			LONITEN						
>D>	AB		PHARMACIA AND UPJOHN	2.5MG	N18154	001		Jan	DISC
>A>			@	2.5MG	N18154	001		Jan	DISC
>D>	AB	+		10MG	N18154	003		Jan	DISC
>A>			@	10MG	N18154	003		Jan	DISC

NIMODIPINE

CAPSULE; ORAL
NIMODIPINE

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

NISOLDIPINE

TABLET, EXTENDED RELEASE; ORAL

SULAR

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

>D> NITROFURAZONE

>D> OINTMENT; TOPICAL

>D> NITROFURAZONE

>D>		+	TARO	0.2%	N86156	001		Jan	DISC
>A>			@	0.2%	N86156	001		Jan	DISC

NYSTATIN

TABLET; ORAL

NYSTATIN

>D>	AA		TEVA	500,000 UNITS	N62506	001	Jan 16, 1984	Jan	CRLD
>A>	AA	+		500,000 UNITS	N62506	001	Jan 16, 1984	Jan	CRLD

OCTREOTIDE ACETATE

INJECTABLE; INJECTION

OCTREOTIDE ACETATE

>D>	AP		BEDFORD	EQ 0.2MG BASE/ML	N76330	001	Apr 08, 2005	Jan	CRLD
>A>	AP	+		EQ 0.2MG BASE/ML	N76330	001	Apr 08, 2005	Jan	CRLD
>D>	AP			EQ 1MG BASE/ML	N76330	002	Apr 08, 2005	Jan	CRLD
>A>	AP	+		EQ 1MG BASE/ML	N76330	002	Apr 08, 2005	Jan	CRLD

OXYCODONE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

OXYCONTIN

>D>			@ PURDUE PHARMA LP	15MG	N20553	006	Sep 18, 2006	Jan	CMFD
>A>				15MG	N20553	006	Sep 18, 2006	Jan	CMFD
>D>			@	30MG	N20553	007	Sep 18, 2006	Jan	CMFD
>A>				30MG	N20553	007	Sep 18, 2006	Jan	CMFD
>D>			@	60MG	N20553	008	Sep 18, 2006	Jan	CMFD
>A>				60MG	N20553	008	Sep 18, 2006	Jan	CMFD

OXYTOCIN

INJECTABLE; INJECTION

OXYTOCIN

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

PALIPERIDONE

TABLET, EXTENDED RELEASE; ORAL

INVEGA

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

PHENDIMETRAZINE TARTRATE

TABLET; ORAL
PHENDIMETRAZINE TARTRATE

>A>	AA	AMIDE PHARM	35MG	N40762	001	Jan 28, 2008	Jan	NEWA

PHENYTOIN SODIUM

CAPSULE; ORAL
EXTENDED PHENYTOIN SODIUM

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

POTASSIUM CHLORIDE

TABLET, EXTENDED RELEASE; ORAL

>D>		K-DUR 10						
>D>	AB	KEY PHARMS	10MEQ	N19439	002	Jun 13, 1986	Jan	CTNA
>D>		K-DUR 20						
>D>	AB +	KEY PHARMS	20MEQ	N19439	001	Jun 13, 1986	Jan	CTNA
>A>		POTASSIUM CHLORIDE						
>A>	AB	SCHERING	10MEQ	N19439	002	Jun 13, 1986	Jan	CTNA
>A>	AB +		20MEQ	N19439	001	Jun 13, 1986	Jan	CTNA

PRAVASTATIN SODIUM

TABLET; ORAL
PRAVASTATIN SODIUM

>A>	AB	LEK PHARMS DD	80MG	N77491	001	Feb 11, 2008	Jan	NEWA
>A>	AB	TEVA PHARMS	80MG	N77793	001	Jan 15, 2008	Jan	NEWA

PREDNISOLONE ACETATE

>A>		SUSPENSION; ORAL						
>A>		FLO-PRED						
>A>		TARO	EQ 5MG BASE/5ML	N22067	001	Jan 17, 2008	Jan	NEWA
>A>	+		EQ 15MG BASE/5ML	N22067	002	Jan 17, 2008	Jan	NEWA

PRIMIDONE

TABLET; ORAL
PRIMIDONE

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

PROCHLORPERAZINE EDISYLATE

INJECTABLE; INJECTION
PROCHLORPERAZINE EDISYLATE

>D>	AP	TEVA PARENTERAL	EQ 5MG BASE/ML	N40505	001	May 30, 2003	Jan	DISC
>A>		@	EQ 5MG BASE/ML	N40505	001	May 30, 2003	Jan	DISC

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL
PROMETHAZINE HYDROCHLORIDE

>A>	AB	IMPAX LABS	12.5MG	N40724	001	Feb 12, 2008	Jan	NEWA
>A>	AB		25MG	N40724	002	Feb 12, 2008	Jan	NEWA

PROPRANOLOL HYDROCHLORIDE

INJECTABLE; INJECTION
PROPRANOLOL HYDROCHLORIDE

>A>	AP	HIKMA FARMACEUTICA	1MG/ML	N77760	001	Jan 31, 2008	Jan	NEWA

SERTRALINE HYDROCHLORIDE

TABLET; ORAL

SERTRALINE HYDROCHLORIDE

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

SOMATROPIN RECOMBINANT

INJECTABLE; INJECTION

ACCRETROPIN

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

NORDITROPIN

>D>		NOVO NORDISK INC	5MG/1.5ML	N21148	001	Jun 20, 2000	Jan	CTEC
>A>	BX		5MG/1.5ML	N21148	001	Jun 20, 2000	Jan	CTEC

NORDITROPIN NORDIFLEX

>D>		NOVO NORDISK INC	5MG/1.5ML	N21148	004	Oct 01, 2004	Jan	CTEC
>A>	BX		5MG/1.5ML	N21148	004	Oct 01, 2004	Jan	CTEC

NUTROPIN AQ

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

NUTROPIN AQ PEN

>D>	BX +	GENENTECH	5MG/ML	N20522	002	Apr 22, 2002	Jan	CPOT
>A>	+		10MG/2ML (5MG/ML)	N20522	002	Apr 22, 2002	Jan	CPOT

OMNITROPE

>A>	BX	SANDOZ	5MG/1.5ML	N21426	003	Jan 16, 2008	Jan	NEWA

TEV-TROPIN

>D>	BX +	FERRING	5MG/ML	N19774	002	Jan 04, 2002	Jan	CPOT
>A>	BX +		5MG/VIAL	N19774	002	Jan 04, 2002	Jan	CPOT

TADALAFIL

TABLET; ORAL

CIALIS

>A>		LILLY	2.5MG	N21368	004	Jan 07, 2008	Jan	NEWA

TECHNETIUM TC-99M MEBROFENIN KIT

INJECTABLE; INJECTION

CHOLETEC

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

TECHNETIUM TC-99M MEBROFENIN

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

VARDENAFIL HYDROCHLORIDE

TABLET; ORAL

LEVITRA

>A>		BAYER HLTHCARE	2.5MG	N21400	003	Aug 19, 2003	Jan	CAHN
>A>			5MG	N21400	001	Aug 19, 2003	Jan	CAHN
>A>			10MG	N21400	002	Aug 19, 2003	Jan	CAHN
>A>	+		20MG	N21400	004	Aug 19, 2003	Jan	CAHN
>D>		BAYER PHARMS	2.5MG	N21400	003	Aug 19, 2003	Jan	CAHN
>D>			5MG	N21400	001	Aug 19, 2003	Jan	CAHN
>D>			10MG	N21400	002	Aug 19, 2003	Jan	CAHN

TABLET; ORAL
LEVITRA

>D>		+	BAYER PHARMS	20MG	N21400	004	Aug 19, 2003	Jan	CAHN

VINORELBINE TARTRATE

INJECTABLE; INJECTION
VINORELBINE TARTRATE

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

ZIDOVUDINE

TABLET; ORAL
ZIDOVUDINE

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

CALCIUM CARBONATE; FAMOTIDINE; MAGNESIUM HYDROXIDE

TABLET, CHEWABLE; ORAL

CALCIUM CARBONATE, FAMOTIDINE AND MAGNESIUM HYDROXIDE

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

CETIRIZINE HYDROCHLORIDE

SYRUP; ORAL

CHILDREN'S ZYRTEC ALLERGY

>A>	+	MCNEIL CONSUMER	1MG/ML	N22155	002	Nov 16, 2007	Jan	CAHN
>D>	+	PFIZER	1MG/ML	N22155	002	Nov 16, 2007	Jan	CAHN

CHILDREN'S ZYRTEC HIVES RELIEF

>A>	+	MCNEIL CONSUMER	1MG/ML	N22155	001	Nov 16, 2007	Jan	CAHN
>D>	+	PFIZER	1MG/ML	N22155	001	Nov 16, 2007	Jan	CAHN

TABLET, CHEWABLE; ORAL

CETIRIZINE HYDROCHLORIDE ALLERGY

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

TABLET; ORAL

CETIRIZINE HYDROCHLORIDE ALLERGY

>A>		DR REDDYS LABS LTD	5MG	N78343	004	Jan 15, 2008	Jan	NEWA
>A>			10MG	N78343	003	Jan 15, 2008	Jan	NEWA

CETIRIZINE HYDROCHLORIDE HIVES

>A>		DR REDDYS LABS LTD	5MG	N78343	001	Jan 15, 2008	Jan	NEWA
>A>			10MG	N78343	002	Jan 15, 2008	Jan	NEWA

ZYRTEC ALLERGY

>A>		MCNEIL CONSUMER	5MG	N19835	003	Nov 16, 2007	Jan	CAHN
>A>	+		10MG	N19835	004	Nov 16, 2007	Jan	CAHN
>D>		PFIZER	5MG	N19835	003	Nov 16, 2007	Jan	CAHN
>D>	+		10MG	N19835	004	Nov 16, 2007	Jan	CAHN

ZYRTEC HIVES RELIEF

>A>		MCNEIL CONSUMER	5MG	N19835	005	Nov 16, 2007	Jan	CAHN
>A>	+		10MG	N19835	006	Nov 16, 2007	Jan	CAHN
>D>		PFIZER	5MG	N19835	005	Nov 16, 2007	Jan	CAHN
>D>	+		10MG	N19835	006	Nov 16, 2007	Jan	CAHN

CETIRIZINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

ZYRTEC-D 12 HOUR

>A>	+	MCNEIL	5MG;120MG	N21150	002	Nov 09, 2007	Jan	CAHN
>D>	+	PFIZER	5MG;120MG	N21150	002	Nov 09, 2007	Jan	CAHN

POTASSIUM IODIDE

TABLET; ORAL

THYROSAFE

>D>	+	R R REGISTRATIONS	65MG	N76350	001	Sep 10, 2002	Jan	CAHN
>A>	+	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 01 JANUARY 2008

NO JANUARY 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 JANUARY 2008 ADDITIONS

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLMENT 1 - January 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
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
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		
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			
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			
COLESEVELAM HYDROCHLORIDE - WELCHOL					
021176 001				**>A>** I-553	Jan 18, 2011
DARIFENACIN HYDROBROMIDE - ENABLEX					
021513 001	**>A>** 5096890	Mar 13, 2015	DS DP	U-631	
DARIFENACIN HYDROBROMIDE - ENABLEX					
021513 002	**>A>** 5096890	Mar 13, 2015	DS DP	U-631	
EPLERENONE - INSPRA					
021437 001				**>A>** M-72	Jan 31, 2011
				>A> PED	Jul 31, 2011

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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
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		
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
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			
LISDEXAMFETAMINE DIMESYLATE - VYVANSE								
021977 006	**>A>** 7105486	Jun	29, 2023			U-842		
	>A> 7223735	Jun	29, 2023		DP			
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			

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APPL/PROD NO	PATENT NO	PATENT EXPIRATON DATE		PATENT CODES		EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
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		
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		
SEVELAMER CARBONATE - RENVELA							
022127 001	**>A>** 5667775	Sep 16, 2014			U-246		
SOMATROPIN RECOMBINANT - ACCRETROPIN							
021538 001						**>A>** NP	Jan 23, 2011
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					
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		
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		

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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.

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