APPROVED DRUG PRODUCTS
With Therapeutic Equivalence Evaluations

The "Orange Book"

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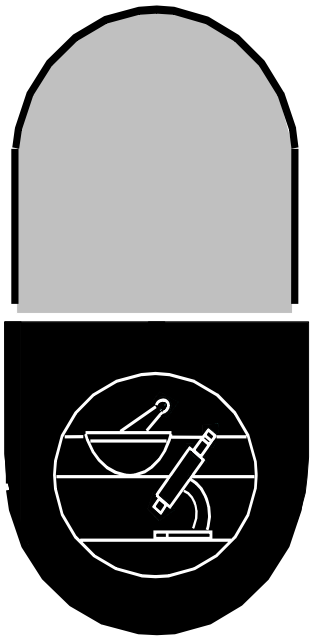
CUMULATIVE SUPPLEMENT 2
FEBRUARY 2005



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

25th EDITION

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs

2005

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

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

25th EDITION

Cumulative Supplement 1

February 2005

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25th EDITION

CUMULATIVE SUPPLEMENT 1
February 2005

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, 25th 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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 25th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 26th 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 Data are indicated by the symbol **>ADD>** to the left of the line on which new information exists. The **>ADD>** 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 Lists are arranged in alphabetical order by active ingredient name. In addition, the trade name will be displayed to the right of the active ingredient name for each product. 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 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)
SHIRE LABORATORIES INC (SHIRE LABS)	SHIRE DEVELOPMENT INC (SHIRE)
SHIRE PHARMACEUTICAL DEVELOPMENT INC (SHIRE PHARM)	SHIRE DEVELOPMENT INC (SHIRE)

1.3 AVAILABILITY OF THE EDITION

Commencing with the 25th edition, the Annual Edition and monthly Cumulative Supplements will not be available in a published paper version. Since 1997, the Electronic Orange Book (EOB http://www.fda.gov/cder/ob/default.htm, has been available on the internet and has become the updated-every-month Orange Book.

By early April, the 25th edition and current monthly supplement will be available in an electronic downloadable Portable Document Format (PDF) at the EOB home page by clicking on the EOB Preface. The PDF annual and cumulative supplements will duplicate previous paper versions. Over time, there will be an archive for the annuals and each year's December Cumulative Supplement.

The Electronic Orange Book Query (EOB) is at http://www.fda.gov/cder/ob/default.htm. 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. Currently, In addition to monthly updates, in the public interest, the EOB is updated on a daily basis with new generic product approval information and new patent information. Current month updates are accomplished by the third week of the following month.

The Internet version of the Orange Book annual edition is at http://www.fda.gov/cder/ob/docs/preface/ectablec.htm The Internet version of the monthly supplement is at http://www.fda.gov/cder/orange/supplement/cspreface.htm .

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 zipped into eobzip.exe. The files are updated concurrently with the monthly cumulative supplements. Appendix A and Appendix B text files of the annual Orange Book Edition are updated quarterly.

The 25th annual edition of the 2005 Orange Book Patent and Exclusivity List is at http://www.fda.gov/cder/orange/24bookpub.pdf.

The current year Patent and Exclusivity cumulative supplement list that denotes the current month additions is at http://www.fda.gov/cder/orange/supplement/patents.pdf.

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.

1.4 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 2004	MAR 2005	JUN 2005	SEP 2005
DRUG PRODUCTS LISTED	11082			

SINGLE SOURCE	2427 (21.9%)
MULTISOURCE	8547 (77.1%)
THERAPEUTICALLY EQUIVALENT	8327 (75.1%)
NOT THERAPEUTICALLY EQUIVALENT	220 (2.0%)
EXCEPTIONS[1]	108 (1.0%)
NEW MOLECULAR ENTITIES APPROVED	9
NUMBER OF APPLICANTS	625

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

1.5 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.
WDAG	Withdrawn. The applicant holder has notified the FDA in writing that the product in no longer being marketed resulting in the product approval being withdrawn by mutual

	agreement. The product will be listed in the Discontinued Section.
WDRP	Withdrawn. The application approval has been withdrawn for failure to provide Annual Reports. The product will be moved to the Discontinued Section in the next edition.

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

TABLET; ORAL

BUTALBITAL, APAP, AND CAFFEINE

>D>	AB	AXIOM PHARM	325MG;50MG;40MG	N89536	001	Feb 16, 1988	Feb	CAHN
>A>	AB	WATSON LABS	325MG;50MG;40MG	N89536	001	Feb 16, 1988	Feb	CAHN

ACETIC ACID, GLACIAL

SOLUTION/DROPS; OTIC

ACETIC ACID

	AT	+ MORTON GROVE	2%	N40166	001	Jul 26, 1996	Jan	CRLD
>A>	AT	VINTAGE	2%	N40607	001	Feb 24, 2005	Feb	NEWA

VOSOL

		@ MEDPOINTE PHARM HLC	2%	N12179	001		Jan	DISC

ACYCLOVIR SODIUM

INJECTABLE; INJECTION

ACYCLOVIR

>D>	AP	ABBOTT	EQ 50MG BASE/ML	N75114	001	Jul 26, 1999	Feb	DISC
>A>		@	EQ 50MG BASE/ML	N75114	001	Jul 26, 1999	Feb	DISC

ALBUTEROL SULFATE

SOLUTION; INHALATION

ALBUTEROL SULFATE

	AN	+ DEY	EQ 0.083% BASE	N72652	001	Feb 21, 1992	Jan	CRLD

ALPRAZOLAM

TABLET, ORALLY DISINTEGRATING; ORAL

NIRAVAM

		SCHWARZ PHARMA	0.25MG	N21726	001	Jan 19, 2005	Jan	NEWA
			0.5MG	N21726	002	Jan 19, 2005	Jan	NEWA
			1MG	N21726	003	Jan 19, 2005	Jan	NEWA
		+	2MG	N21726	004	Jan 19, 2005	Jan	NEWA

AMOXICILLIN; CLAVULANATE POTASSIUM

FOR SUSPENSION; ORAL

AMOXICILLIN AND CLAVULANATE POTASSIUM

	AB	HIKMA PHARMS	200MG/5ML;EQ 28.5MG BASE/5ML	N65191	002	Jan 25, 2005	Jan	NEWA
	AB		400MG/5ML;EQ 57MG BASE/5ML	N65191	001	Jan 25, 2005	Jan	NEWA

TABLET, CHEWABLE; ORAL

AMOXICILLIN AND CLAVULANATE POTASSIUM

	AB	TEVA	200MG;EQ 28.5MG BASE	N65205	001	Feb 09, 2005	Jan	NEWA
	AB		400MG;EQ 57MG BASE	N65205	002	Feb 09, 2005	Jan	NEWA

AMPICILLIN SODIUM

INJECTABLE; INJECTION

AMPICILLIN SODIUM

	AP	INSTITUTO BIOCHEMICO	EQ 125MG BASE/VIAL	N62797	001	Jul 12, 1993	Jan	CMFD
	AP		EQ 2GM BASE/VIAL	N62797	002	Jul 12, 1993	Jan	CAHN

ATENOLOL

TABLET; ORAL

ATENOLOL

	AB	ZYDUS PHARMS USA	25MG	N76900	001	Jan 28, 2005	Jan	NEWA

TABLET; ORAL
ATENOLOL

AB	ZYDUS PHARMS USA	50MG	N76900	002	Jan 28, 2005	Jan	NEWA
AB		100MG	N76900	003	Jan 28, 2005	Jan	NEWA

ATOMOXETINE HYDROCHLORIDE

CAPSULE; ORAL
STRATTERA

>A>	LILLY	80MG	N21411	007	Feb 14, 2005	Feb	NEWA
>A>		100MG	N21411	008	Feb 14, 2005	Feb	NEWA

BETAMETHASONE DIPROPIONATE

OINTMENT; TOPICAL
ALPHATREX

	@ SAVAGE LABS	EQ 0.05% BASE	N19143	001	Sep 04, 1984	Jan	DISC

BUPRENORPHINE HYDROCHLORIDE

INJECTABLE; INJECTION
BUPRENORPHINE HCL

>A>	AP	BEDFORD	EQ 0.3MG BASE/ML	N76931	001	Mar 02, 2005	Feb	NEWA

CAFFEINE; ERGOTAMINE TARTRATE

SUPPOSITORY; RECTAL
MIGERGOT

>D>		@ G AND W LABS	100MG;2MG	N86557	001	Oct 04, 1983	Feb	CMFD
>A>	BR		100MG;2MG	N86557	001	Oct 04, 1983	Feb	CMFD

CEPHALEXIN

CAPSULE; ORAL
CEPHALEXIN

AB	BELCHER	EQ 250MG BASE	N62713	001	Jul 15, 1988	Jan	CAHN
AB		EQ 500MG BASE	N62713	002	Jul 15, 1988	Jan	CAHN
AB	SUN PHARM INDS (IN)	EQ 250MG BASE	N62791	001	Jun 11, 1987	Jan	CAHN
AB		EQ 500MG BASE	N62791	002	Jun 11, 1987	Jan	CAHN
>A>	AB	YUNG SHIN PHARM	EQ 250MG BASE	N65152	001	Feb 24, 2005	Feb	NEWA
>A>	AB		EQ 500MG BASE	N65152	002	Feb 24, 2005	Feb	NEWA

CILOSTAZOL

TABLET; ORAL
CILOSTAZOL

>A>	AB	COREPHARMA	50MG	N77150	001	Mar 11, 2005	Feb	NEWA
>A>	AB	IVAX PHARMS	100MG	N77020	002	Mar 01, 2005	Feb	NEWA

CIPROFLOXACIN HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
CIPROFLOXACIN

AT	HITECH PHARMA	EQ 0.3% BASE	N76673	001	Jan 21, 2005	Jan	NEWA

TABLET; ORAL
CIPROFLOXACIN

AB	COBALT	EQ 100MG BASE	N76794	001	Feb 10, 2005	Jan	NEWA
>A>	AB	SANDOZ	EQ 100MG BASE	N75939	001	Mar 03, 2005	Feb	NEWA
AB	TARO	EQ 100MG BASE	N76912	001	Feb 18, 2005	Jan	NEWA

CITALOPRAM HYDROBROMIDE

TABLET; ORAL
CITALOPRAM HYDROBROMIDE

	AB	MYLAN	EQ 10MG BASE	N77039	001	Feb 03, 2005	Jan	NEWA
	AB		EQ 20MG BASE	N77039	002	Feb 03, 2005	Jan	NEWA
	AB		EQ 40MG BASE	N77039	003	Feb 03, 2005	Jan	NEWA

CLARITHROMYCIN

TABLET, EXTENDED RELEASE; ORAL
CLARITHROMYCIN

		RANBAXY	1GM	N65210	001	Jan 26, 2005	Jan	NEWA

TABLET; ORAL
CLARITHROMYCIN

>A>	AB	GENPHARM	250MG	N65195	001	Mar 11, 2005	Feb	NEWA
>A>	AB		500MG	N65195	002	Mar 11, 2005	Feb	NEWA

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL
CLINDAMYCIN HYDROCHLORIDE

	AB	ZYDUS PHARMS USA	EQ 75MG BASE	N65217	001	Jan 31, 2005	Jan	NEWA
	AB		EQ 150MG BASE	N65217	002	Jan 31, 2005	Jan	NEWA
	AB		EQ 300MG BASE	N65217	003	Jan 31, 2005	Jan	NEWA

CLOTRIMAZOLE

CREAM; TOPICAL
CLOTRIMAZOLE

>D>	AB	TARO	1%	N72640	001	Aug 31, 1993	Feb	CRLD
>A>	+		1%	N72640	001	Aug 31, 1993	Feb	CRLD
>D>		LOTRIMIN						
>D>	AB	+ SCHERING PLOUGH	1%	N17619	001		Feb	DISC
>A>		@	1%	N17619	001		Feb	DISC
>D>		MYCELEX						
>D>	BT	BAYER PHARMS	1%	N18183	001		Feb	DISC
>A>		@	1%	N18183	001		Feb	DISC

CYANOCOBALAMIN

SPRAY, METERED; NASAL
NASCOBAL

>D>	+	NASTECH PHARM	0.5MG/SPRAY	N21642	001	Jan 31, 2005	Feb	CAHN
	+		0.5MG/SPRAY	N21642	001	Jan 31, 2005	Jan	NEWA
>A>	+	QUESTCOR PHARMS	0.5MG/SPRAY	N21642	001	Jan 31, 2005	Feb	CAHN

CYPROHEPTADINE HYDROCHLORIDE

TABLET; ORAL
CYPROHEPTADINE HCL

>D>	AA	ABC HOLDING	4MG	N88212	001	May 26, 1983	Feb	DISC
>A>		@	4MG	N88212	001	May 26, 1983	Feb	DISC

DALTEPARIN SODIUM

INJECTABLE; INJECTION
FRAGMIN

	+	PHARMACIA AND UPJOHN	7,500 IU/0.3ML	N20287	005	Apr 04, 2002	Jan	NEWA

DANTROLENE SODIUM

CAPSULE; ORAL

			DANTRIUM							
>D>			PROCTER AND GAMBLE	25MG	N17443	001			Feb	CFTG
>A>	AB			25MG	N17443	001			Feb	CFTG
>D>				50MG	N17443	003			Feb	CFTG
>A>	AB			50MG	N17443	003			Feb	CFTG
>D>		+		100MG	N17443	002			Feb	CFTG
>A>	AB	+		100MG	N17443	002			Feb	CFTG
>A>			DANTROLENE SODIUM							
>A>	AB		IMPAX LABS	25MG	N76856	001	Mar 01, 2005		Feb	NEWA
>A>	AB			50MG	N76856	002	Mar 01, 2005		Feb	NEWA
>A>	AB			100MG	N76856	003	Mar 01, 2005		Feb	NEWA

DESMOPRESSIN ACETATE

SPRAY, METERED; NASAL

			DESMOPRESSIN ACETATE (NEEDS NO REFRIGERATION)							
	AB		APOTEX	0.01MG/SPRAY	N76703	001	Jan 27, 2005		Jan	NEWA

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL

>D>			DIETHYLPROPION HCL							
>D>	AA		ABC HOLDING	25MG	N88267	001	Aug 25, 1983		Feb	DISC
>A>			@	25MG	N88267	001	Aug 25, 1983		Feb	DISC
>D>	AA			25MG	N88268	001	Aug 25, 1983		Feb	DISC
>A>			@	25MG	N88268	001	Aug 25, 1983		Feb	DISC
			TENUATE							
>D>	AA	+	AVENTIS PHARMS	25MG	N11722	002			Feb	CTEC
>A>		+		25MG	N11722	002			Feb	CTEC

DOXAZOSIN MESYLATE

TABLET, EXTENDED RELEASE; ORAL

>A>			CARDURA XL							
>A>			PFIZER	EQ 4MG BASE	N21269	001	Feb 22, 2005		Feb	NEWA
>A>		+		EQ 8MG BASE	N21269	002	Feb 22, 2005		Feb	NEWA

ENALAPRIL MALEATE

TABLET; ORAL

			ENALAPRIL MALEATE							
>D>	AB		APOTHECON	2.5MG	N75583	001	Aug 22, 2000		Feb	DISC
>A>			@	2.5MG	N75583	001	Aug 22, 2000		Feb	DISC
>D>	AB			5MG	N75583	002	Aug 22, 2000		Feb	DISC
>A>			@	5MG	N75583	002	Aug 22, 2000		Feb	DISC
>D>	AB			10MG	N75583	003	Aug 22, 2000		Feb	DISC
>A>			@	10MG	N75583	003	Aug 22, 2000		Feb	DISC
>D>	AB			20MG	N75583	004	Aug 22, 2000		Feb	DISC
>A>			@	20MG	N75583	004	Aug 22, 2000		Feb	DISC

EPINEPHRINE

INJECTABLE; IM-SC

>D>			TWINJECT							
>D>		+	HOLLISTER STIER LABS	EQ 0.3MG /DELIVERY	N20800	001	May 30, 2003		Feb	CTNA
>A>			TWINJECT 0.30							
>A>		+	HOLLISTER STIER LABS	EQ 0.3MG /DELIVERY	N20800	001	May 30, 2003		Feb	CTNA

ERYTHROMYCIN

SOLUTION; TOPICAL

ERYMAX

AT		MERZ PHARMS	2%	N62508	002	Jul 11, 1985	Jan		CAHN

ERYTHROMYCIN ESTOLATE

CAPSULE; ORAL

ERYTHROMYCIN ESTOLATE

>D>	+	BARR	EQ 250MG BASE	N62162	002		Feb		DISC
>A>		@	EQ 250MG BASE	N62162	002		Feb		DISC

ESOMEPRAZOLE MAGNESIUM

CAPSULE, DELAYED REL PELLETS; ORAL

NEXIUM

		ASTRAZENECA	EQ 20MG BASE	N21153	001	Feb 20, 2001	Jan		CRLD

ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL

CLIMARA

AB2	+	BERLEX	0.025MG/24HR	N20375	004	Mar 05, 1999	Jan		CFTG
AB2	+		0.075MG/24HR	N20375	003	Mar 23, 1998	Jan		CFTG

ESCLIM

		@ WOMEN FIRST HLTHCARE	0.025MG/24HR	N20847	001	Aug 04, 1998	Jan		DISC
		@	0.0375MG/24HR	N20847	002	Aug 04, 1998	Jan		DISC
		@	0.05MG/24HR	N20847	003	Aug 04, 1998	Jan		DISC
		@	0.075MG/24HR	N20847	004	Aug 04, 1998	Jan		DISC
		@	0.1MG/24HR	N20847	005	Aug 04, 1998	Jan		DISC

ESTRADIOL

AB2		MYLAN TECHNOLOGIES	0.025MG/24HR	N75182	003	Jan 26, 2005	Jan		NEWA
AB2			0.075MG/24HR	N75182	002	Jan 26, 2005	Jan		NEWA

VIVELLE

		@ NOVARTIS	0.025MG/24HR	N20323	005	Aug 16, 2000	Jan		DISC
AB1			0.05MG/24HR	N20323	002	Oct 28, 1994	Jan		CRLD
AB1			0.1MG/24HR	N20323	004	Oct 28, 1994	Jan		CRLD

VIVELLE-DOT

BX	+	NOVARTIS	0.025MG/24HR	N20538	009	May 03, 2002	Jan		CRLD
BX	+		0.0375MG/24HR	N20538	005	Jan 08, 1999	Jan		CRLD
AB1	+		0.05MG/24HR	N20538	006	Jan 08, 1999	Jan		CRLD
BX	+		0.075MG/24HR	N20538	007	Jan 08, 1999	Jan		CRLD
AB1	+		0.1MG/24HR	N20538	008	Jan 08, 1999	Jan		CRLD

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-28

ORTHO-NOVUM 7/14-28

>D>									
>D>	AB	+ ORTHO MCNEIL PHARM	0.035MG,0.035MG;0.5MG,1MG	N19004	002	Apr 04, 1984	Feb		DISC
>A>		@	0.035MG,0.035MG;0.5MG,1MG	N19004	002	Apr 04, 1984	Feb		DISC

FENOLDOPAM MESYLATE

INJECTABLE; INJECTION

FENOLDOPAM MESYLATE

AP		SABEX 2002	EQ 10MG BASE/ML	N77155	001	Feb 15, 2005	Jan		NEWA

FENTANYL

FILM, EXTENDED RELEASE; TRANSDERMAL

			DURAGESIC-100						
	AB		ALZA	100UGM/HR	N19813	001	Aug 07, 1990	Jan	CFTG
			DURAGESIC-12						
>A>			ALZA	12.5UGM/HR	N19813	005	Feb 04, 2005	Feb	NEWA
			DURAGESIC-25						
	AB	+	ALZA	25UGM/HR	N19813	004	Aug 07, 1990	Jan	CFTG
			DURAGESIC-50						
	AB		ALZA	50UGM/HR	N19813	003	Aug 07, 1990	Jan	CFTG
			DURAGESIC-75						
	AB		ALZA	75UGM/HR	N19813	002	Aug 07, 1990	Jan	CFTG
			FENTANYL						
	AB		MYLAN TECHNOLOGIES	25UGM/HR	N76258	001	Jan 28, 2005	Jan	NEWA
	AB			50UGM/HR	N76258	002	Jan 28, 2005	Jan	NEWA
	AB			75UGM/HR	N76258	003	Jan 28, 2005	Jan	NEWA
	AB			100UGM/HR	N76258	004	Jan 28, 2005	Jan	NEWA

FLUOCINONIDE

CREAM; TOPICAL

>A>			VANOS						
>A>		+	MEDICIS	0.1%	N21758	001	Feb 11, 2005	Feb	NEWA

FLUTICASONE PROPIONATE

AEROSOL, METERED; INHALATION

			FLOVENT						
		+	GLAXOSMITHKLINE	0.044MG/INH	N20548	001	Mar 27, 1996	Jan	CRLD
		+		0.11MG/INH	N20548	002	Mar 27, 1996	Jan	CRLD
			FLOVENT HFA						
		+	GLAXOSMITHKLINE	0.044MG/INH	N21433	003	May 14, 2004	Jan	CRLD
		+		0.11MG/INH	N21433	002	May 14, 2004	Jan	CRLD

FOLLITROPIN ALFA/BETA

INJECTABLE; SUBCUTANEOUS

			FOLLISTIM AQ						
>A>		+	ORGANON USA INC	150 IU/0.18ML	N21211	003	Feb 11, 2004	Feb	NEWA
		+		300 IU/0.36ML	N21211	001	Mar 23, 2004	Jan	CPOT
		+		600 IU/0.72ML	N21211	002	Mar 23, 2004	Jan	CPOT
>A>		+		900 IU/1.08ML	N21211	004	Feb 11, 2005	Feb	NEWA

>D> FOMIVIRSEN SODIUM

>D> INJECTABLE; INJECTION

>D> VITRAVENE PRESERVATIVE FREE

>D>		+	NOVARTIS	6.6MG/ML	N20961	001	Aug 26, 1998	Feb	DISC
>A>		@		6.6MG/ML	N20961	001	Aug 26, 1998	Feb	DISC

FUROSEMIDE

INJECTABLE; INJECTION

			FUROSEMIDE						
>D>	AP		LUITPOLD	10MG/ML	N18579	001	Nov 30, 1983	Feb	CRLD
>A>	AP	+		10MG/ML	N18579	001	Nov 30, 1983	Feb	CRLD
>D>			LASIX						
>D>	AP	+	AVENTIS PHARMS	10MG/ML	N16363	001		Feb	DISC
>A>		@		10MG/ML	N16363	001		Feb	DISC

GALANTAMINE HYDROBROMIDE

CAPSULE, EXTENDED RELEASE; ORAL

REMINYL

		+	JOHNSON AND JOHNSON	EQ 8MG BASE	N21615	001	Dec 22, 2004	Jan	CRLD
				EQ 24MG BASE	N21615	003	Dec 22, 2004	Jan	CRLD

GLYBURIDE; METFORMIN HYDROCHLORIDE

TABLET; ORAL

GLYBURIDE AND METFORMIN HCL

	AB		TEVA	1.25MG;250MG	N76821	001	Jan 27, 2005	Jan	NEWA
	AB			2.5MG;500MG	N76821	002	Jan 27, 2005	Jan	NEWA
	AB			5MG;500MG	N76821	003	Jan 27, 2005	Jan	NEWA

GONADOTROPIN, CHORIONIC

INJECTABLE; INJECTION

CHORIONIC GONADOTROPIN

>D>		@	STERIS	2,000 UNITS/VIAL	N17016	009	Dec 27, 1984	Feb	CAHN
>D>		@		2,000 UNITS/VIAL	N17016	011	Feb 16, 1990	Feb	CAHN
>D>		@		5,000 UNITS/VIAL	N17016	006		Feb	CAHN
>D>	AP	+		10,000 UNITS/VIAL	N17016	007		Feb	CAHN
>D>		@		15,000 UNITS/VIAL	N17016	010	Feb 15, 1985	Feb	CAHN
>D>		@		20,000 UNITS/VIAL	N17016	004		Feb	CAHN
>A>		@	WATSON LABS (UTAH)	2,000 UNITS/VIAL	N17016	009	Dec 27, 1984	Feb	CAHN
>A>		@		2,000 UNITS/VIAL	N17016	011	Feb 16, 1990	Feb	CAHN
>A>		@		5,000 UNITS/VIAL	N17016	006		Feb	CAHN
>A>	AP	+		10,000 UNITS/VIAL	N17016	007		Feb	CAHN
>A>		@		15,000 UNITS/VIAL	N17016	010	Feb 15, 1985	Feb	CAHN
>A>		@		20,000 UNITS/VIAL	N17016	004		Feb	CAHN

GRISEOFULVIN, MICROCRYSTALLINE

SUSPENSION; ORAL

GRIFULVIN V

>D>		+	J AND J	125MG/5ML	N62483	001	Jan 26, 1984	Feb	CFTG
>A>	AB	+		125MG/5ML	N62483	001	Jan 26, 1984	Feb	CFTG

>A> GRISEOFULVIN

>A>	AB		STIEFEL	125MG/5ML	N65200	001	Mar 02, 2005	Feb	NEWA

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE

SYRUP; ORAL

HYDROCODONE BITARTRATE AND HOMATROPINE METHYLBROMIDE

	AA		IVAX PHARMS	1.5MG/5ML;5MG/5ML	N40285	001	Jul 19, 1999	Jan	CAHN

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

HYDRALAZINE HCL

>D>	AA		ABC HOLDING	10MG	N88846	001	Feb 26, 1985	Feb	DISC
>A>		@		10MG	N88846	001	Feb 26, 1985	Feb	DISC
>D>	AA			25MG	N88847	001	Feb 26, 1985	Feb	DISC
>A>		@		25MG	N88847	001	Feb 26, 1985	Feb	DISC
>D>	AA			50MG	N88848	001	Feb 26, 1985	Feb	DISC
>A>		@		50MG	N88848	001	Feb 26, 1985	Feb	DISC
>D>	AA			100MG	N88849	001	Feb 26, 1985	Feb	DISC
>A>		@		100MG	N88849	001	Feb 26, 1985	Feb	DISC

HYDROCHLOROTHIAZIDE

TABLET; ORAL

HYDROCHLOROTHIAZIDE

>D>	AB		ABC HOLDING	25MG	N85683	001		Feb	DISC
>A>		@		25MG	N85683	001		Feb	DISC
>D>	AB			50MG	N83965	001		Feb	DISC
>A>		@		50MG	N83965	001		Feb	DISC
>D>	AB			50MG	N85672	001		Feb	DISC
>A>		@		50MG	N85672	001		Feb	DISC

HYDROMORPHONE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

PALLADONE

>D>		+	PURDUE PHARMA LP	16MG	N21044	002	Sep 24, 2004	Feb	CRLD
>A>				16MG	N21044	002	Sep 24, 2004	Feb	CRLD
>D>				32MG	N21044	004	Sep 24, 2004	Feb	CRLD
>A>		+		32MG	N21044	004	Sep 24, 2004	Feb	CRLD

IBANDRONATE SODIUM

TABLET; ORAL

BONIVA

>D>		@	ROCHE	EQ 2.5MG BASE	N21455	001	May 16, 2003	Feb	CMFD
>A>		+		EQ 2.5MG BASE	N21455	001	May 16, 2003	Feb	CMFD

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL

IMIPRAMINE HCL

>D>	AB		TEVA	10MG	N83729	001		Feb	DISC
>A>		@		10MG	N83729	001		Feb	DISC
>D>	AB			25MG	N83729	004		Feb	DISC
>A>		@		25MG	N83729	004		Feb	DISC
>D>	AB			50MG	N83729	003		Feb	DISC
>A>		@		50MG	N83729	003		Feb	DISC

IRON DEXTRAN

INJECTABLE; INJECTION

INFED

>D>	BP	+	SCHEIN	EQ 50MG IRON/ML	N17441	001		Feb	CAHN
>A>	BP	+	WATSON LABS (UTAH)	EQ 50MG IRON/ML	N17441	001		Feb	CAHN

KANAMYCIN SULFATE

CAPSULE; ORAL

KANTREX

>D>		+	APOTHECON	EQ 500MG BASE	N62726	001	Mar 06, 1987	Feb	DISC
>A>		@		EQ 500MG BASE	N62726	001	Mar 06, 1987	Feb	DISC

LEUPROLIDE ACETATE

INJECTABLE; SUBCUTANEOUS

ELIGARD

		+	QLT USA	22.5MG/VIAL	N21379	001	Jul 24, 2002	Jan	CAHN

LEVOFLOXACIN

TABLET; ORAL

LEVAQUIN

	AB	+	ORTHO MCNEIL PHARM	750MG	N20634	003	Sep 08, 2000	Jan	CFTG

TABLET; ORAL
LEVOFLOXACIN

AB		TEVA	750MG	N76361	003	Jan 26, 2005	Jan	NEWA

LORAZEPAM

SOLUTION; ORAL
LORAZEPAM

		ROXANE	0.5MG/5ML	N74648	001	Mar 18, 1997	Jan	CMFD

MANGAFODIPIR TRISODIUM

INJECTABLE; INJECTION
TESLASCAN

		@ GE HEALTHCARE	37.9MG/ML	N20652	001	Nov 26, 1997	Jan	DISC

MECLIZINE HYDROCHLORIDE

TABLET; ORAL
MECLIZINE HCL

>D>	AA	ABC HOLDING	12.5MG	N85253	001		Feb	DISC
>A>		@	12.5MG	N85253	001		Feb	DISC
>D>	AA		25MG	N85252	001		Feb	DISC
>A>		@	25MG	N85252	001		Feb	DISC

MEQUINOL; TRETINOIN

SOLUTION; TOPICAL
SOLAGE

>A>	+	BARRIER	2%;0.01%	N20922	001	Dec 10, 1999	Feb	CAHN
>D>	+	GALDERMA LABS	2%;0.01%	N20922	001	Dec 10, 1999	Feb	CAHN

METHIMAZOLE

TABLET; ORAL
METHIMAZOLE

AB		CEDAR PHARMS	5MG	N40547	001	Feb 18, 2005	Jan	NEWA
AB			10MG	N40547	002	Feb 18, 2005	Jan	NEWA
AB			20MG	N40547	004	Feb 18, 2005	Jan	NEWA
AB	+	GENPHARM	20MG	N40350	003	Jun 07, 2001	Jan	CFTG

METHYLDOPA

TABLET; ORAL
ALDOMET

		@ MERCK	500MG	N13400	002		Jan	DISC

METHYLDOPA

AB	+	MYLAN	500MG	N70076	001	Apr 18, 1985	Jan	CRLD

METHYLDOPATE HYDROCHLORIDE

INJECTABLE; INJECTION
ALDOMET

		@ MERCK	50MG/ML	N13401	001		Jan	DISC

METHYLDOPATE HCL

AP	+	LUITPOLD	50MG/ML	N71279	001	Oct 02, 1987	Jan	CRLD

METHYLERGONOVINE MALEATE

TABLET; ORAL
METHERGINE

	+	NOVARTIS	0.2MG	N06035	003		Jan	CRLD

METHYLPREDNISOLONE ACETATE

INJECTABLE; INJECTION

DEPO-MEDROL

>D>		+	PHARMACIA AND UPJOHN	40MG/ML	N11757	001		Feb	CFTG
>A>	AB	+		40MG/ML	N11757	001		Feb	CFTG
>D>		+		80MG/ML	N11757	004		Feb	CFTG
>A>	AB	+		80MG/ML	N11757	004		Feb	CFTG

>A> METHYLPREDNISOLONE ACETATE

>A>	AB	SICOR PHARMS	40MG/ML	N40557	001	Feb 23, 2005	Feb	NEWA
>A>	AB		80MG/ML	N40557	002	Feb 23, 2005	Feb	NEWA

MIDAZOLAM HYDROCHLORIDE

INJECTABLE; INJECTION

MIDAZOLAM HCL

	AP	INTL MEDICATED	EQ 1MG BASE/ML	N76144	001	Jan 26, 2005	Jan	NEWA
	AP		EQ 5MG BASE/ML	N76144	002	Jan 26, 2005	Jan	NEWA

MOMETASONE FUROATE

CREAM; TOPICAL

ELOCON

	AB	+ SCHERING	0.1%	N19625	001	May 06, 1987	Jan	CFTG

MOMETASONE FUROATE

	AB	TARO	0.1%	N76679	001	Dec 21, 2004	Jan	NEWA

OXALIPLATIN

INJECTABLE; IV (INFUSION)

ELOXATIN

		+ SANOFI SYNTHELABO	50MG/10ML (5MG/ML)	N21759	001	Jan 31, 2005	Jan	NEWA
		+	100MG/20ML (5MG/ML)	N21759	002	Jan 31, 2005	Jan	NEWA

PACLITAXEL

FOR SUSPENSION; IV (INFUSION)

ABRAXANE

		+ AM BIOSCIENCE	100MG/VIAL	N21660	001	Jan 07, 2005	Jan	NEWA

PENTOBARBITAL SODIUM

CAPSULE; ORAL

SODIUM PENTOBARBITAL

		@ VALEANT PHARM INTL	100MG	N83264	001		Jan	DISC

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

BONTRIL PDM

>D>	AA	VALEANT	35MG	N85272	001		Feb	CRLD
>A>	AA	+	35MG	N85272	001		Feb	CRLD

>D> CAM-METRAZINE

>D>	AA	+ ABC HOLDING	35MG	N83922	001		Feb	DISC
>A>		@	35MG	N83922	001		Feb	DISC
>D>	AA		35MG	N85318	001		Feb	DISC
>A>		@	35MG	N85318	001		Feb	DISC
>D>	AA		35MG	N85320	001		Feb	DISC
>A>		@	35MG	N85320	001		Feb	DISC
>D>	AA		35MG	N85321	001		Feb	DISC
>A>		@	35MG	N85321	001		Feb	DISC
>D>	AA		35MG	N85511	001		Feb	DISC

		TABLET; ORAL							
>D>		CAM-METRAZINE							
>A>		@ ABC HOLDING	35MG	N85511	001			Feb	DISC
>D>	AA	CAMALL	35MG	N85756	001			Feb	DISC
>A>		@	35MG	N85756	001			Feb	DISC
		PHENDIMETRAZINE TARTRATE							
>D>	AA	ABC HOLDING	35MG	N85761	001			Feb	DISC
>A>		@	35MG	N85761	001			Feb	DISC
>D>	AA		35MG	N85941	001	Jun 27, 1983		Feb	DISC
>A>		@	35MG	N85941	001	Jun 27, 1983		Feb	DISC
>D>	AA	EON	35MG	N85830	001			Feb	DISC
>A>		@	35MG	N85830	001			Feb	DISC
>D>		X-TROZINE							
>D>	AA	SHIRE RICHWOOD	35MG	N86553	001			Feb	DISC
>A>		@	35MG	N86553	001			Feb	DISC
>D>	AA		35MG	N86554	001			Feb	DISC
>A>		@	35MG	N86554	001			Feb	DISC
		PHENTERMINE HYDROCHLORIDE							
		CAPSULE; ORAL							
>D>		ONA-MAST							
>D>	AA	MAST MM	30MG	N86511	001			Feb	DISC
>A>		@	30MG	N86511	001			Feb	DISC
>D>	AA		30MG	N86516	001			Feb	DISC
>A>		@	30MG	N86516	001			Feb	DISC
		PHENTERMINE HCL							
>D>		ABC HOLDING	18.75MG	N88576	001	May 23, 1984		Feb	DISC
>A>		@	18.75MG	N88576	001	May 23, 1984		Feb	DISC
>D>	AA		30MG	N85417	001			Feb	DISC
>A>		@	30MG	N85417	001			Feb	DISC
>D>	AA		30MG	N86732	002			Feb	DISC
>A>		@	30MG	N86732	002			Feb	DISC
>D>	AA		30MG	N87215	001			Feb	DISC
>A>		@	30MG	N87215	001			Feb	DISC
>D>	AA		37.5MG	N87915	001	Dec 22, 1983		Feb	DISC
>A>		@	37.5MG	N87915	001	Dec 22, 1983		Feb	DISC
>D>	AA		37.5MG	N87918	001	Dec 22, 1983		Feb	DISC
>A>		@	37.5MG	N87918	001	Dec 22, 1983		Feb	DISC
>D>	AA		37.5MG	N87930	001	Oct 14, 1983		Feb	DISC
>A>		@	37.5MG	N87930	001	Oct 14, 1983		Feb	DISC
>D>	AA		37.5MG	N88610	001	Jun 04, 1984		Feb	DISC
>A>		@	37.5MG	N88610	001	Jun 04, 1984		Feb	DISC
>D>	AA		37.5MG	N88611	001	Jun 04, 1984		Feb	DISC
>A>		@	37.5MG	N88611	001	Jun 04, 1984		Feb	DISC
>D>	AA		37.5MG	N88625	001	Aug 23, 1984		Feb	DISC
>A>		@	37.5MG	N88625	001	Aug 23, 1984		Feb	DISC
>D>	AA	CAMALL	15MG	N86735	001			Feb	DISC
>A>		@	15MG	N86735	001			Feb	DISC
>D>	AA		30MG	N87226	001			Feb	DISC
>A>		@	30MG	N87226	001			Feb	DISC
		TABLET; ORAL							
>D>		ONA MAST							
>D>	AA	MAST MM	8MG	N86260	001			Feb	DISC
>A>		@	8MG	N86260	001			Feb	DISC
		PHENTERMINE HCL							
>D>	AA	+ ABC HOLDING	8MG	N83923	001			Feb	DISC
>A>		@	8MG	N83923	001			Feb	DISC

TABLET; ORAL
PHENTERMINE HCL

>D>	AA	ABC HOLDING	8MG	N85319	001		Feb	DISC
>A>		@	8MG	N85319	001		Feb	DISC
>D>	AA		37.5MG	N87805	001	Dec 06, 1982	Feb	DISC
>A>		@	37.5MG	N87805	001	Dec 06, 1982	Feb	DISC
>D>	AA		37.5MG	N88596	001	Apr 04, 1984	Feb	DISC
>A>		@	37.5MG	N88596	001	Apr 04, 1984	Feb	DISC

POTASSIUM CITRATE

TABLET, EXTENDED RELEASE; ORAL
UROCIT-K

		MISSION PHARMA	5MEQ	N19071	001	Aug 30, 1985	Jan	CTNA
	+		10MEQ	N19071	002	Aug 31, 1992	Jan	CTNA

PREDNISOLONE

SYRUP; ORAL
PREDNISOLONE

	AA	IVAX PHARMS	15MG/5ML	N40287	001	May 28, 1999	Jan	CAHN

PRIMIDONE

TABLET; ORAL
PRIMIDONE

>A>	AB	VINTAGE PHARMS	50MG	N40586	001	Feb 24, 2005	Feb	NEWA
>A>	AB		250MG	N40586	002	Feb 24, 2005	Feb	NEWA

PROGESTERONE

INJECTABLE; INJECTION
PROGESTERONE

>D>	AO	+ SCHEIN	50MG/ML	N17362	002		Feb	CAHN
>A>	AO	+ WATSON LABS (UTAH)	50MG/ML	N17362	002		Feb	CAHN

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL
PROMETHAZINE HCL

		ABLE	12.5MG	N40558	001	Jul 01, 2004	Jan	CTEC

QUINAPRIL HYDROCHLORIDE

TABLET; ORAL
QUINAPRIL HCL

>A>	AB	EON	EQ 5MG BASE	N76803	001	Mar 02, 2005	Feb	NEWA
>A>	AB		EQ 10MG BASE	N76803	002	Mar 02, 2005	Feb	NEWA
>A>	AB		EQ 20MG BASE	N76803	003	Mar 02, 2005	Feb	NEWA
>A>	AB		EQ 40MG BASE	N76803	004	Mar 02, 2005	Feb	NEWA
	AB	PAR PHARM	EQ 5MG BASE	N76036	001	Jan 28, 2005	Jan	NEWA
	AB		EQ 10MG BASE	N76036	002	Jan 28, 2005	Jan	NEWA
	AB		EQ 20MG BASE	N76036	003	Jan 28, 2005	Jan	NEWA
	AB		EQ 40MG BASE	N76036	004	Jan 28, 2005	Jan	NEWA

RANITIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
RANITIDINE HCL

>A>	AP	BEN VENUE	EQ 25MG BASE/ML	N74777	001	Mar 02, 2005	Feb	NEWA

>A>		SODIUM BENZOATE; SODIUM PHENYLACETATE							
>A>		SOLUTION; IV (INFUSION)							
>A>		AMMONUL							
>A>	+	UCYCLYD	10%;10% (5GM/50ML;5GM/50ML)	N20645	001	Feb 17, 2005	Feb	NEWA	
		SOMATROPIN RECOMBINANT							
>A>		INJECTABLE; SUBCUTANEOUS							
>A>		SEROSTIM LQ							
>A>		SERONO	6MG/0.05VIAL	N20604	005	Feb 11, 2005	Feb	NEWA	
		SULFAMETHOXAZOLE; TRIMETHOPRIM							
		TABLET; ORAL							
		SULFAMETHOXAZOLE AND TRIMETHOPRIM							
	AB	INTERPHARM	400MG;80MG	N76899	001	Jan 27, 2005	Jan	NEWA	
	AB		800MG;160MG	N76899	002	Jan 27, 2005	Jan	NEWA	
		TACROLIMUS							
		CAPSULE; ORAL							
		PROGRAF							
	+	FUJISAWA HLTHCARE	EQ 1MG BASE	N50708	001	Apr 08, 1994	Jan	CRLD	
		TAMOXIFEN CITRATE							
		TABLET; ORAL							
		TAMOXIFEN CITRATE							
>D>	AB	PHARMACHEMIE	EQ 10MG BASE	N74539	001	Mar 31, 2003	Feb	DISC	
>A>		@	EQ 10MG BASE	N74539	001	Mar 31, 2003	Feb	DISC	
		TELITHROMYCIN							
		TABLET; ORAL							
		KETEK							
>A>		AVENTIS PHARMS	300MG	N21144	002	Feb 09, 2005	Feb	NEWA	
		TERCONAZOLE							
		CREAM; VAGINAL							
		TERCONAZOLE							
	AB	ALTANA	0.4%	N76712	001	Feb 18, 2005	Jan	NEWA	
		TESTOSTERONE CYPIONATE							
		INJECTABLE; INJECTION							
		TESTOSTERONE CYPIONATE							
	AO	PADDOCK	200MG/ML	N40530	001	Jan 31, 2005	Jan	NEWA	
		TETRACYCLINE HYDROCHLORIDE							
		CAPSULE; ORAL							
		TETRACYCLINE HCL							
>D>	AB	MAST MM	250MG	N62085	001		Feb	DISC	
>A>		@	250MG	N62085	001		Feb	DISC	
		TOREMIFENE CITRATE							
		TABLET; ORAL							
		FARESTON							
	+	GTX INC	EQ 60MG BASE	N20497	001	May 29, 1997	Jan	CAHN	

TORSEMIDE

TABLET; ORAL

TORSEMIDE

>A>	AB	ROXANE	5MG	N76943	001	Mar 01, 2005	Feb	NEWA
>A>	AB		10MG	N76943	002	Mar 01, 2005	Feb	NEWA
>A>	AB		20MG	N76943	003	Mar 01, 2005	Feb	NEWA

>D> TRICHLORMETHIAZIDE

>D> TABLET; ORAL

>D> NAQUA

>D>	BP	+ SCHERING	4MG	N12265	002		Feb	DISC
>A>		@	4MG	N12265	002		Feb	DISC

TRICHLORMETHIAZIDE

>D>	BP	ABC HOLDING	4MG	N85568	001		Feb	DISC
>A>		@	4MG	N85568	001		Feb	DISC
>D>	BP	PAR PHARM	2MG	N87007	001		Feb	DISC
>A>		@	2MG	N87007	001		Feb	DISC
>D>	BP		4MG	N87005	001		Feb	DISC
>A>		@	4MG	N87005	001		Feb	DISC

TRIMETHOPRIM HYDROCHLORIDE

SOLUTION; ORAL

PRIMSOL

@ TARO PHARMS NORTH	EQ 25MG BASE/5ML	N74374	001	Jun 23, 1995	Jan	CAHN
+	EQ 50MG BASE/5ML	N74973	001	Jan 24, 2000	Jan	CAHN

FAMOTIDINE

TABLET; ORAL

FAMOTIDINE

>A>	WOCKHARDT	10MG	N77146	001	Mar 07, 2005	Feb	NEWA

LORATADINE

SYRUP; ORAL

CLARITIN HIVES RELIEF

	@ SCHERING	1MG/ML	N20641	003	Nov 19, 2003	Jan	DISC

MICONAZOLE NITRATE

CREAM; VAGINAL

MICONAZOLE 3

>A>	TARO	4%	N76773	001	Mar 02, 2005	Feb	NEWA

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

CUMULATIVE SUPPLEMENT NUMBER 01 FEBRUARY 2005

NO FEBRUARY 2005 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

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DRUG PRODUCTS WHICH MUST DEMONSTRATE *IN VIVO* BIOAVAILABILITY ONLY IF PRODUCT FAILS TO ACHIEVE ADEQUATE DISSOLUTION

NO FEBRUARY 2005 ADDITIONS

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	PATENT CODE(S)	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	021457 001	ALBUTEROL SULFATE;ALBUTEROL SULFATE HF	5605674	FEB 25, 2014	DP		
>ADD>			5695743	JUL 06, 2010	DP		
>ADD>			6352684	NOV 28, 2009	DP		
>ADD>	021726 001	ALPRAZOLAM;NIRAVAM	6221392	APR 09, 2018	DP		
>ADD>			6024981	APR 09, 2018	DP		
>ADD>	021726 002	ALPRAZOLAM;NIRAVAM	6221392	APR 09, 2018	DP		
>ADD>			6024981	APR 09, 2018	DP		
>ADD>	021726 003	ALPRAZOLAM;NIRAVAM	6221392	APR 09, 2018	DP		
>ADD>			6024981	APR 09, 2018	DP		
>ADD>	021726 004	ALPRAZOLAM;NIRAVAM	6221392	APR 09, 2018	DP		
>ADD>			6024981	APR 09, 2018	DP		
>ADD>	021713 001	ARIPIPRAZOLE;ABILIFY				NCE	NOV 15, 2007
>ADD>						I-437	SEP 29, 2007
>ADD>						I-401	AUG 28, 2006
>ADD>	021248 001	ARSENIC TRIOXIDE;TRISENOX	6855339	NOV 10, 2018	U617		
>ADD>			6861076	NOV 10, 2018	U617		
>ADD>	021411 007	ATOMOXETINE HYDROCHLORIDE;STRATTERA				NCE	NOV 26, 2007
>ADD>						PED	MAY 26, 2008
>ADD>	021411 008	ATOMOXETINE HYDROCHLORIDE;STRATTERA				NCE	NOV 26, 2007
>ADD>						PED	MAY 26, 2008
>ADD>	020838 001	CANDESARTAN CILEXETIL;ATACAND				I-448	FEB 22, 2008
>ADD>	020838 002	CANDESARTAN CILEXETIL;ATACAND				I-448	FEB 22, 2008
>ADD>	020838 003	CANDESARTAN CILEXETIL;ATACAND				I-448	FEB 22, 2008
>ADD>	020838 004	CANDESARTAN CILEXETIL;ATACAND				I-448	FEB 22, 2008
	021710 001	CARBAMAZEPINE;EQUETRO	5326570	JUL 23, 2011	DP U627		
			5912013	JUN 15, 2016	DP		
	021710 002	CARBAMAZEPINE;EQUETRO	5326570	JUL 23, 2011	DP U627		
			5912013	JUN 15, 2016	DP		
	021710 003	CARBAMAZEPINE;EQUETRO	5326570	JUL 23, 2011	DP U627		
			5912013	JUN 15, 2016	DP		
	021673 001	CLOFARABINE;CLOLAR	5661136	AUG 26, 2014	U626		
			5384310	MAY 23, 2009	DS DP		
			4918179	JUN 14, 2005	DS		
>ADD>	021572 001	DAPTOMYCIN;CUBICIN	6852689	SEP 24, 2019	U282		
>ADD>	021572 002	DAPTOMYCIN;CUBICIN	6852689	SEP 24, 2019	U282		
>ADD>	021605 001	DESLORATADINE;CLARINEX D 24 HOUR				NCE	DEC 21, 2006
>ADD>						PED	JUN 21, 2007
>ADD>	076068 001	DEXRAZOXANE HYDROCHLORIDE;DEXRAZOXANE				PC	AUG 27, 2005
	021168 001	DIVALPROEX SODIUM;DEPAKOTE ER	6720004	DEC 18, 2018	DP		
	021168 002	DIVALPROEX SODIUM;DEPAKOTE ER	6720004	DEC 18, 2018	DP		
>ADD>	021269 001	DOXAZOSIN MESYLATE;CARDURA XL				NDF	FEB 22, 2008
>ADD>	021269 002	DOXAZOSIN MESYLATE;CARDURA XL				NDF	FEB 22, 2008
>ADD>	021437 001	EPLERENONE;INSPRA	4559332	APR 09, 2005	DS DP U537		
>ADD>	021437 002	EPLERENONE;INSPRA	4559332	APR 09, 2005	DS DP U537		
>ADD>	021437 003	EPLERENONE;INSPRA	4559332	APR 09, 2005	DS DP U537		
	021337 001	ERTAPENEM SODIUM;INVANZ	5478820	FEB 02, 2013		NCE	NOV 21, 2006
			5652233	FEB 02, 2013		PED	MAY 21, 2007
			5952323	MAY 15, 2017			
			5478820*PED	AUG 02, 2013			
			5652233*PED	AUG 02, 2013			
			5952323*PED	NOV 15, 2017			
	076323 001	ESMOLOL HYDROCHLORIDE;ESMOLOL HCL				PC	MAY 01, 2005

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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	PATENT CODE(S)	EXCLUS CODE	EXCLUS EXPIRES
	021476 001	ESZOPICLONE;LUNESTA	6444673	JAN 16, 2012	DS DP		
			6319926	JAN 16, 2012	U620		
	021476 002	ESZOPICLONE;LUNESTA	6444673	JAN 16, 2012	DS DP		
			6319926	JAN 16, 2012	U620		
	021476 003	ESZOPICLONE;LUNESTA	6444673	JAN 16, 2012	DS DP		
			6319926	JAN 16, 2012	U620		
>ADD>	021712 001	FAMOTIDINE;FLUXID	6024981	APR 09, 2018	DP		
>ADD>			6221392	APR 09, 2018	DP		
>ADD>	021712 002	FAMOTIDINE;FLUXID	6024981	APR 09, 2018	DP		
>ADD>			6221392	APR 09, 2018	DP		
	020747 001	FENTANYL CITRATE;ACTIQ	5785989	MAY 01, 2005			
	020747 002	FENTANYL CITRATE;ACTIQ	5785989	MAY 01, 2005			
	020747 003	FENTANYL CITRATE;ACTIQ	5785989	MAY 01, 2005			
	020747 004	FENTANYL CITRATE;ACTIQ	5785989	MAY 01, 2005			
	020747 005	FENTANYL CITRATE;ACTIQ	5785989	MAY 01, 2005			
	020747 006	FENTANYL CITRATE;ACTIQ	5785989	MAY 01, 2005			
>ADD>	019813 005	FENTANYL;DURAGESIC-12				NPP	MAY 20, 2006
>ADD>						PED	NOV 20, 2006
>ADD>	021758 001	FLUOCINONIDE;VANOS				NP	FEB 11, 2008
	021077 002	FLUTICASONE PROPIONATE;ADVAIR DISKUS 250/50	6536427	MAR 01, 2011	DP		
	021169 001	GALANTAMINE HYDROBROMIDE;REMINYL	6358527	JUN 06, 2017	DP U322		
	021169 002	GALANTAMINE HYDROBROMIDE;REMINYL	6358527	JUN 06, 2017	DP U322		
	021169 003	GALANTAMINE HYDROBROMIDE;REMINYL	6358527	JUN 06, 2017	DP U322		
	020509 001	GEMCITABINE HYDROCHLORIDE;GEMZAR	4808614	MAY 15, 2010	DS	I-428	MAY 19, 2007
			5464826	NOV 07, 2012	U146	PED	NOV 19, 2007
			4808614*PED	NOV 15, 2010			
			5464826*PED	MAY 07, 2013			
	020509 002	GEMCITABINE HYDROCHLORIDE;GEMZAR	5464826	NOV 07, 2012	U146	I-428	MAY 19, 2007
			4808614	MAY 15, 2010	DS	PED	NOV 19, 2007
			4808614*PED	NOV 15, 2010			
			5464826*PED	MAY 07, 2013			
>ADD>	020239 003	GRANISETRON HYDROCHLORIDE;KYTRIL	4886808	DEC 29, 2007	DS DP U89	I-369	AUG 16, 2005
	020239 004	GRANISETRON HYDROCHLORIDE;KYTRIL				I-369	AUG 16, 2005
	021335 001	IMATINIB MESYLATE;GLEEVEC	5521184	JAN 04, 2015			
	021335 002	IMATINIB MESYLATE;GLEEVEC	5521184	JAN 04, 2015			
	021588 001	IMATINIB MESYLATE;GLEEVEC	5521184	JAN 04, 2015			
	021588 002	IMATINIB MESYLATE;GLEEVEC	5521184	JAN 04, 2015			
	020726 001	LETROZOLE;FEMARA				I-446	OCT 29, 2007
	021731 001	LEUPROLIDE ACETATE;ELIGARD	RE37950	OCT 03, 2008	DP U621		
			4938763	OCT 03, 2008	DP U621		
			5278201	JAN 11, 2011	DP		
			5324519	JUN 28, 2011	DP		
			5599552	FEB 04, 2014	DP U621		
			5739176	OCT 03, 2008	DP U621		
			6395293	SEP 28, 2013	DP		
			6565874	OCT 28, 2018	DP U621		
			6626870	MAR 27, 2020	DP		
			6773714	OCT 28, 2018	U621		
	021130 001	LINEZOLID;ZYVOX	5688792	NOV 18, 2014	DS U319	NCE	APR 18, 2005
			6559305	JAN 29, 2021	DS	NPP	DEC 19, 2005
			6514529	MAR 15, 2021	DP	I-402	JUL 22, 2006
			5688792*PED	MAY 18, 2015		I-431	JUN 23, 2007
			6514529*PED	SEP 15, 2021		PED	JAN 22, 2007
			6559305*PED	JUL 29, 2021		PED	OCT 18, 2005
						PED	DEC 23, 2007
						PED	JUN 19, 2006

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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	PATENT CODE(S)	EXCLUS CODE	EXCLUS EXPIRES
	021130 002	LINEZOLID;ZYVOX	5688792	NOV 18, 2014	DS U319	NCE	APR 18, 2005
			6559305	JAN 29, 2021	DS	NPP	DEC 19, 2005
			6514529	MAR 15, 2021	DP	I-402	JUL 22, 2006
			5688792*PED	MAY 18, 2015		I-431	JUN 23, 2007
			6514529*PED	SEP 15, 2021		PED	JAN 22, 2007
			6559305*PED	JUL 29, 2021		PED	OCT 18, 2005
						PED	DEC 23, 2007
						PED	JUN 19, 2006
	021131 001	LINEZOLID;ZYVOX	5688792	NOV 18, 2014	U319	NCE	APR 18, 2005
			6559305	JAN 29, 2021	DS	NPP	DEC 19, 2005
			5688792*PED	MAY 18, 2015		I-402	JUL 22, 2006
			6559305*PED	JUL 29, 2021		I-431	JUN 23, 2007
						PED	JUN 19, 2006
						PED	JAN 22, 2007
						PED	OCT 18, 2005
						PED	DEC 23, 2007
	021132 001	LINEZOLID;ZYVOX	5688792	NOV 18, 2014	DS U319	NCE	APR 18, 2005
			6559305	JAN 29, 2021	DS	NPP	DEC 19, 2005
			5688792*PED	MAY 18, 2015		I-402	JUL 22, 2006
			6559305*PED	JUL 29, 2021		I-431	JUN 23, 2007
						PED	OCT 18, 2005
						PED	JAN 22, 2007
						PED	DEC 23, 2007
						PED	JUN 19, 2006
	021583 001	MEDROXYPROGESTERONE ACETATE;DEPO-SUBQ PROVERA 10	6495534	MAY 15, 2020	DP		
	076863 001	METFORMIN HYDROCHLORIDE;METFORMIN HCL				PC	APR 12, 2005
>ADD>	019962 001	METOPROLOL SUCCINATE;TOPROL-XL	5001161	SEP 18, 2007		D-95	FEB 15, 2008
			5081154	SEP 18, 2007			
>ADD>	019962 002	METOPROLOL SUCCINATE;TOPROL-XL	5001161	SEP 18, 2007		D-95	FEB 15, 2008
			5081154	SEP 18, 2007			
>ADD>	019962 003	METOPROLOL SUCCINATE;TOPROL-XL	5001161	SEP 18, 2007		D-95	FEB 15, 2008
			5081154	SEP 18, 2007			
>ADD>	019962 004	METOPROLOL SUCCINATE;TOPROL-XL	5081154	SEP 18, 2007	U107	D-95	FEB 15, 2008
			5001161	SEP 18, 2007	U107		
	020762 001	MOMETASONE FUROATE MONOHYDRATE;NASONEX	5837699	JAN 27, 2014	DP U625		
			6127353	OCT 03, 2017	DS DP		
			6723713	JAN 27, 2014	U625		
	021204 001	NATEGLINIDE;STARLIX	RE34878	SEP 08, 2009			
			6844008	NOV 14, 2017	DP U214		
	021204 002	NATEGLINIDE;STARLIX	RE34878	SEP 08, 2009			
			6844008	NOV 14, 2017	DP U214		
	021706 001	OMEPRAZOLE;ZEGERID	5840737	JUL 16, 2016	DS U623		
			6489346	JUL 16, 2016	DS DP U624		
			6645988	JUL 16, 2016	DS DP U623		
			6780882	JUL 16, 2016	DS DP U624		
			6699885	JUL 16, 2016			
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>ADD>	021759 001	OXALIPLATIN;ELOXATIN				NCE	AUG 09, 2007
>ADD>						I-441	NOV 04, 2007
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>ADD>						I-441	NOV 04, 2007

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>ADD>	021014 001	OXCARBAZEPINE;TRILEPTAL				NCE	JAN 14, 2005
>ADD>						PED	JUL 14, 2005
>ADD>	021014 002	OXCARBAZEPINE;TRILEPTAL				NCE	JAN 14, 2005
>ADD>						PED	JUL 14, 2005
>ADD>	021014 003	OXCARBAZEPINE;TRILEPTAL				NCE	JAN 14, 2005
>ADD>						PED	JUL 14, 2005
>ADD>	021285 001	OXCARBAZEPINE;TRILEPTAL				NCE	JAN 14, 2005
>ADD>						PED	JUL 14, 2005
	021660 001	PACLITAXEL;ABRAXANE				NP	JAN 07, 2008
	021756 001	PEGAPTANIB SODIUM;MACUGEN	6051698	SEP 17, 2012	DS		
			5919455	OCT 27, 2013	DS		
			5932462	AUG 03, 2016	DS		
			6113906	OCT 27, 2013	DS		
			6011020	JAN 04, 2017	DS		
			6426335	JUN 11, 2010	U622		
			6147204	JUN 11, 2010	DS		
	021446 001	PREGABALIN;LYRICA	6001876	JUL 16, 2017	U55		
			6197819	MAR 06, 2018	DS DP		
	021446 002	PREGABALIN;LYRICA	6001876	JUL 16, 2017	U55		
			6197819	MAR 06, 2018	DS DP		
	021446 003	PREGABALIN;LYRICA	6001876	JUL 16, 2017	U55		
			6197819	MAR 06, 2018	DS DP		
	021446 004	PREGABALIN;LYRICA	6001876	JUL 16, 2017	U55		
			6197819	MAR 06, 2018	DS DP		
	021446 005	PREGABALIN;LYRICA	6001876	JUL 16, 2017	U55		
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	021446 006	PREGABALIN;LYRICA	6001876	JUL 16, 2017	U55		
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	021446 007	PREGABALIN;LYRICA	6001876	JUL 16, 2017	U55		
			6197819	MAR 06, 2018	DS DP		
	021446 008	PREGABALIN;LYRICA	6001876	JUL 16, 2017	U55		
			6197819	MAR 06, 2018	DS DP		
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>ADD>						ODE	FEB 17, 2012
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>ADD>	020505 006	TOPIRAMATE;TOPAMAX				I-41	AUG 11, 2007
>ADD>	020844 001	TOPIRAMATE;TOPAMAX SPRINKLE				I-41	AUG 11, 2007
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			5795864	JUN 27, 2015	DP U55		
			5859186	DEC 30, 2011			
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					U55		
>ADD>	021060 002	ZICONOTIDE;PRIALT	5364842	DEC 30, 2011	U48		
			5795864	JUN 27, 2015	DP U55		
			5859186	DEC 30, 2011			
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					U55		

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>ADD>	021060 003	ZICONOTIDE;PRIALT	5364842	DEC 30, 2011	U48		
			5795864	JUN 27, 2015	DP U55		
			5859186	DEC 30, 2011			
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>ADD>	021060 004	ZICONOTIDE;PRIALT	5364842	DEC 30, 2011	U48		
			5795864	JUN 27, 2015	DP U55		
			5859186	DEC 30, 2011			
					U48		
					U55		

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 submitted on FDA Form 3542 and listed after August 18, 2003 will have one to three patent codes indicating specific patent claims as submitted by the sponsor:
   DS = Drug Substance claim
   DP = Drug Product claim
   U and number = Method of Use claim (may be multiple). Specific Method of use claims are listed at http://www.fda.gov/cder/orange/patex.htm

3. 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.

4. *PED and PED represent pediatric exclusivity. Patents with pediatric exclusivity granted after August 18, 2003 will be indicated with *PED as was done prior to August 18, 2003. Patents with *PED added after August 18, 2003 will not contain any information relative to the patent itself other than the *PED extension. Information related specifically to the patent will be conveyed on the original patent only.

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, 25th Edition for a full listing of patent and exclusivity terms (Abbreviations, Dosing Schedule, Indications, and Patent Use Codes).

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

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