APPROVED DRUG PRODUCTS
With Therapeutic Equivalence Evaluations

The "Orange Book"

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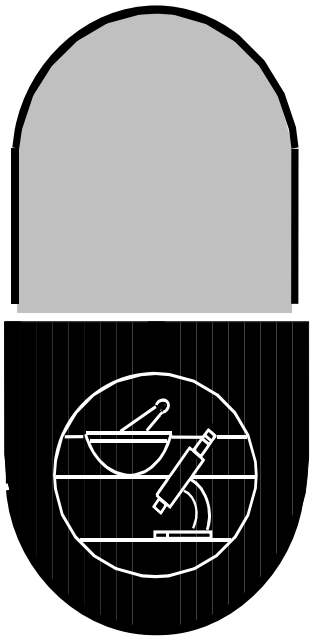
CUMULATIVE SUPPLEMENT 05
May 2006



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

26th EDITION

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

2006

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

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Note:
Historically, the Electronic Orange Book (EOB) and Cumulative Supplement (CS) have been updated monthly, each month updated by the end of the second full working week of the following month.

As of February 2005, we are also providing daily EOB product information for new generic drug approvals. Daily generic updates will provide the consumer with the most current listing of approved generic products. Previously, a first-time-generic approved early in the month would not be published in the CS for several weeks. Daily generic updates are especially important since the Orange Book listing may be relevant for substitution.

As a result, the monthly CS will include generic approvals and related product changes current to the day of publication (e.g., the June CS will include generic approvals up to the second week of July). Patent information is also current to the day of publication.

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CUMULATIVE SUPPLEMENT 05
May 2006

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 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 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)
APOTEX CORP (APOTEX)	APOTEX INC ETOBICOKE SITE (APOTEX INC)
APOTEX CORP (APOTEX)	APOTEX INC RICHMOND HILL (APOTEX INC)

APOTEX INC (APOTEX)	APOTEX INC ETOBICOKE SITE (APOTEX INC)
APOTEX INC (APOTEX)	APOTEX INC RICHMOND HILL (APOTEX INC)
APOTEX INC (APOTEX INC)	APOTEX INC ETOBICOKE SITE (APOTEX INC)
APOTEX INC (APOTEX INC)	APOTEX INC RICHMOND HILL (APOTEX INC)
AVENTIS PHARMACEUTICALS INC (AVENTIS)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
AVENTIS PHARMACEUTICAL PRODUCTS INC (AVENTIS PHARMS)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
DERMIK LABORATORIES DIV AVENTIS PHARMACEUTICALS INC (DERMIK LABS)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
DERMIK LABORATORIES INC (DERMIK LABS)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
DERMIK LABORATORIES INC SUB RORER (DERMIK LABS)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
CLAY PARK LABORATORIES INC (CLAY PARK)	PERRIGO NEW YORK INC (PERRIGO NEW YORK)
CLAY PARK LABS INC (CLAY PARK)	PERRIGO NEW YORK INC (PERRIGO NEW YORK)
LOREX PHARMACEUTICALS (LOREX)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
MARTEC PHARMACEUTICALS (MARTEC)	MARTEC USA LLC (MARTEC USA LLC)
MARTEC SCIENTIFIC INC (MARTEC)	MARTEC USA LLC (MARTEC USA LLC)
PRIVATE FORMULATIONS INC (PRIVATE FMLTNS)	LEINER HEALTH PRODUCTS INC (LEINER HLTH PRODS)
PHARMACEUTICAL FORMULATIONS INC (PHARM FORM)	LEINER HEALTH PRODUCTS INC (LEINER HLTH PRODS)
SANKYO PHARMA INC (SANKYO)	DAIICHI SANKYO INC (DAIICHI SANKYO)
SANOFI AVENTIS US INC (SANOFI AVENTIS US)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
SANOFI-AVENTIS US INC (SANOFI AVENTIS)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
SANOFI INC (SANOFI)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
SANOFI SYNTHELABO INC (SANOFI SYNTHELABO)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
SANOFI SYNTHELABO RESEARCH DIV SANOFI SYNTHELABO INC (SANOFI SYN RES)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
STERIS LABORATORIES INC (STERIS)	WATSON LABORATORIES INC (WATSON)
TRIGEN LABORATORIES INC (TRIGEN)	JUBILANT PHARMACEUTICALS INC (JUBILANT PHARMS)
UCB PHARMA INC (UCB PHARMA)	UCB INC (UCB INC)

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.

The 25th edition and current monthly supplement are available in an electronic downloadable Portable Document Format (PDF) at the EOB home page by clicking on the Annual Edition. 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.

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.

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 2005	MAR 2006	SEP 2006	DEC 2006
DRUG PRODUCTS LISTED	11368	11487		
SINGLE SOURCE	2428	2461		
	(21.4%)	(21.4%)		
MULTISOURCE	8851	8937		
	(77.9%)	(77.8%)		
THERAPEUTICALLY EQUIVALENT	8642	8730		
	(76.04%)	(76.0%)		
NOT THERAPEUTICALLY EQUIVALENT	209	207		
	(1.8%)	(1.8%)		
EXCEPTIONS[1]	89	89		
	(0.8%)	(0.8%)		
NEW MOLECULAR ENTITIES APPROVED	11	6		
NUMBER OF APPLICANTS	628	629		

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

1.5 ZOCOR (SIMVASTATIN) PATENT RELISTING

U.S. Patent Nos. RE 36481 and RE 36520 are being relisted for Zocor (NDA 19-766) pursuant to the decision and related order in *Ranbaxy Labs. v.Leavitt,* No. 05-1838 (D.D.C. April 30, 2006). The '481 and '520 patents will remain listed in *Approved Drug Products with Therapeutic Equivalence Ratings* until any applicable periods of exclusivity pursuant to section *505(j)(5)(B)(iv)* of the Federal Food, Drug, and Cosmetic Act have been triggered and run, unless the agency's appeal of the decision to the U.S. Court of Appeals for the District of Columbia is decided in the agency's favor before the exclusivity periods have expired. While the patents remain listed, any new or pending ANDA referencing Zocor must contain patent certifications to these patents. For additional information on this matter, please refer to Docket Nos. 2005P-0008 and 2005P-0046.

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.
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