Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA approved for marketing the human drug product ANGIOMAX (bivalirudin). ANGIOMAX is indicated for use as an anticoagulant in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ANGIOMAX (U.S. Patent No. 5,196,404) from The Medicines Company, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 6, 2001, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period, that the approval of ANGIOMAX represented the first permitted commercial marketing or use of the product, and that the patent term restoration application was untimely within the meaning of 35 U.S.C. section 156(d)(1).

On August 3, 2010, in *The Medicines Company* v. *David Kappos et al.,* Civil Action No. 01:10-cv-286, the United States District Court for the Eastern District of Virginia, Alexandria Division, ordered the United States Patent and Trademark Office to consider The Medicines Company's patent term restoration application for ANGIOMAX to have been timely filed. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ANGIOMAX is 3,665 days. Of this time, 2,576 days occurred during the testing phase of the regulatory review period, while 1,089 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* December 5, 1990. The applicant claims November 2, 1990, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 5, 1990, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* December 23, 1997. FDA has verified the applicant's claim that the new drug application (NDA) for ANGIOMAX (NDA 20–873) was submitted on December 23, 1997.

3. *The date the application was approved:* December 15, 2000. FDA has verified the applicant's claim that NDA 20–873 was approved on December 15, 2000.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,773 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments and ask for a redetermination by February 14, 2011. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by June 14, 2011. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (*See* H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) electronic or written comments and written petitions. It is only necessary to send one set of comments. It is no longer necessary to send three copies of mailed comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document.

Comments and petitions that have not been made publicly available on regulations.gov may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 22, 2010.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2010–31583 Filed 12–15–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0605]

Small Entity Compliance Guide: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary

Supplements—Small Entity Compliance Guide." The small entity compliance guide (SECG) is being issued for a final rule and an interim final rule published in the **Federal Register** of June 25, 2007, and is intended to set forth in plain language the requirements of that final rule and interim final rule and to help small businesses understand the regulations. In addition, the SECG includes several recommendations made by FDA in that final rule so that the guidance in those recommendations will be readily accessible to small businesses.

DATES: Submit either electronic or written comments on the SECG at any time.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments on the SECG to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the SECG to the Division of Dietary Supplement Programs (HFS–810), Office of Nutrition, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your requests. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

FOR FURTHER INFORMATION CONTACT: Bradford Williams, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1440.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 25, 2007 (72 FR 34752), FDA issued a final rule establishing current good manufacturing practice (CGMP) regulations for dietary supplements (21 CFR part 111) (the DS CGMP final rule). The DS CGMP final rule requires persons who manufacture, package, label, or hold a dietary supplement to establish and follow current good manufacturing practice to ensure the quality of the dietary supplement and to ensure that the dietary supplement is packaged and labeled as specified in the master manufacturing record. In that same issue of the **Federal Register** (72 FR 34959), FDA also issued an interim final rule (the identity testing interim final rule) that sets forth a procedure for requesting an exemption from a requirement for the manufacturer to conduct at least one appropriate test or examination to verify the identity of any dietary ingredient that is a component of a dietary supplement. The final rule and the identity testing interim final rule became effective August 24, 2007. The compliance date of the DS CGMP final rule and the identity testing interim final rule is June 25, 2008; except that for businesses employing fewer than 500, but 20 or more full-time equivalent employees, the compliance date is June 25, 2009; and except that for businesses that employ fewer than 20 full-time equivalent employees, the compliance date is June 25, 2010.

FDA examined the economic implications of the DS CGMP final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612) and determined that the DS CGMP final rule would have a significant economic impact on a substantial number of small entities. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121), FDA is making available this SECG stating in plain language the requirements of the regulations. We also examined the economic implications of the identity testing interim final rule as required by the Regulatory Flexibility Act and determined that the identity testing interim final rule would not have a significant economic impact on a substantial number of small entities. However, because the identity testing interim final rule revises the DS CGMP final rule, the SECG includes the provisions of the identity testing interim final rule.

FDA is issuing this SECG as level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115(c)(2)).[1] The SECG restates, in simplified format and language, FDA's requirements for Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, including the requirements for a Petition to Request an Exemption from 100 Percent Identity Testing of Dietary Ingredients. In addition, the SECG includes several recommendations made by FDA in the DS CGMP rule so that the guidance in those recommendations will be readily accessible to small businesses.

The SECG represents FDA's current thinking on current good manufacturing practice in manufacturing, packaging, labeling, or holding operations for dietary supplements. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations. We note, however, that the regulations that serve as the basis for this guidance document establish requirements for all covered activities. For this reason, we recommend that affected parties consult the regulations at 21 CFR part 111 in addition to reading the SECG.

[1] We note that the American Herbal Products Association submitted a petition for reconsideration on July 25, 2007, under 21 CFR 10.33, requesting reconsideration of certain provisions of the DS CGMP final rule. FDA is currently considering this petition and the SECG does not represent a response to such petition.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 111 have been approved under 0910–0606.

III. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments on the SECG. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the SECG at *http://www.fda.gov/FoodGuidances.html* or *http://www.regulations.gov.*

Dated: December 13, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–31613 Filed 12–15–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.