TABLE 2.—TOTAL ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

FDA Center	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Center for Food Safety and Applied Nutrition	1,794	5	8,970	2	17,940
Total	14,853		24,272		39,333

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimates were averaged based on the approximate number of requests for certificates the agency received over the past 3 years. The burden estimate for the Center for Drug Evaluation and Research was increased to reflect a more accurate average number of requests for certificates.

Dated: February 23, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–4457 Filed 3–2–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–E–0308]

Determination of Regulatory Review Period for Purposes of Patent Extension; ENDEAVOR

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ENDEAVOR and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

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

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 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. 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 (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device, ENDEAVOR (Zotarolimus-Eluting Coronary Stent System). ENDEAVOR is indicated for improving coronary luminal diameter in patients with ischemic heart disease due to *de novo* lesions of length ≤27 millimeters (mm) in native coronary arteries with reference vessel diameters of ≥2.5 mm to ≤3.5 mm. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ENDEAVOR (U.S. Patent No. 5,624,411) from Medtronic, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated June 19, 2008, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of ENDEAVOR represented the first permitted commercial marketing or use of the product. 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 ENDEAVOR is 1,507 days. Of this time, 1,068 days occurred during the testing phase of the regulatory review period, while 439 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) involving this device became effective*: December 19, 2003. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the act for human tests to begin became effective was December 19, 2003.

2. *The date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e)*: November 20, 2006. The applicant claims November 16, 2006, as the date the premarket approval application (PMA) for ENDEAVOR (PMA P060033) was initially submitted. However, FDA records indicate that PMA P060033 was submitted on November 20, 2006.

3. *The date the application was approved*: February 1, 2008. FDA has verified the applicant's claim that PMA P060033 was approved on February 1, 2008.

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 954 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**) written or electronic comments and ask for a redetermination by May 4, 2009. 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 August 31, 2009. 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.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 17, 2009.

Jane A. Axelrad,

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

[FR Doc. E9–4374 Filed 3–2–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0095]

Draft Guidance for Industry on the Clinical Pharmacology Section of Labeling for Human Prescription Drug and Biological Products—Content and Format; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Clinical Pharmacology Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.'' This draft guidance is one of a series of guidance documents intended to assist applicants in complying with new FDA regulations on the content and format of labeling for human prescription drug and biological products. The draft guidance describes the recommended information to include in the *Clinical pharmacology* section of labeling that pertains to the safe and effective use of human prescription drug and biological products.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by June 1, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send two self-addressed adhesive labels to assist the office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Paul Hepp, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1270, Silver Spring, MD 20993–0002, 301–796–1538; or

Lei Zhang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 3106, Silver Spring, MD 20993–0002, 301–796–1635; or

Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17),Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 24, 2006 (71 FR 3922), FDA published a final rule entitled ''Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products,'' to revise the agency's previous regulations on labeling (effective June 30, 2006). The new FDA regulations are designed to make information in prescription drug labeling easier for health care practitioners to access, read, and use, thereby increasing the extent to which practitioners rely on labeling for prescribing decisions. Among other things, the new FDA regulations require that the *Clinical pharmacology* section of the labeling contain the following subsections: *Mechanism of action*, *Pharmacodynamics*, and *Pharmacokinetics*(§ 201.57(c)(13)(i) (21 CFR 201.57(c)(13)(i)).

FDA is announcing the availability of a draft guidance for industry entitled ''Clinical Pharmacology Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.'' The draft guidance is intended to assist applicants in producing the *Clinical pharmacology* section of labeling for human prescription drug and biological products that is consistent, understandable, organized, clinically useful, and in compliance with the new requirements of § 201.57(c)(13)(i). The ultimate goal of the guidance is to optimize patient drug therapy.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the content and format of the clinical pharmacology section of labeling for human prescription drug and biological products. 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.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of