The purpose of this analysis is to facilitate public comment on the proposed Decision and Order. This analysis is not intended to constitute an official interpretation of the Consent Agreement and the proposed Decision and Order, and does not modify their terms in any way. Further, the proposed Consent Agreement has been entered into for settlement purposes only, and does not constitute an admission by Respondents that they violated the law or that the facts alleged in the complaint (other than jurisdictional facts) are true.

By direction of the Commission.

**Donald S. Clark,**

*Secretary.*

[FR Doc. E9–4481 Filed 3–2–09: 8:45 am]

**[BILLING CODE 6750–01–S]**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institute for Occupational Safety and Health; Decision To Evaluate a Petition To Designate a Class of Employees for the Oak Ridge Hospital, Oak Ridge, TN, To Be Included in the Special Exposure Cohort

**AGENCY:** National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** HHS gives notice as required by 42 CFR 83.12(e) of a decision to evaluate a petition to designate a class of employees for the Oak Ridge Hospital, Oak Ridge, Tennessee, to be included in the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000. The initial proposed definition for the class being evaluated, subject to revision as warranted by the evaluation, is as follows:

*Facility:* Oak Ridge Hospital.

*Location:* Oak Ridge, Tennessee.

*Job Titles and/or Job Duties:* All employees.

*Period of Employment:* June 30, 1958 through December 31, 1959.

**FOR FURTHER INFORMATION CONTACT:** Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 513–533–6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to *OCAS@CDC.GOV*.

**Christine M. Branche,**

*Acting Director, National Institute for Occupational Safety and Health.*

[FR Doc. E9–4493 Filed 3–2–09; 8:45 am]

**BILLING CODE 4163–19–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention (CDC)

### Request for Nominations of Candidates To Serve on the Board of Scientific Counselors, Coordinating Center for Infectious Diseases (BSC, CCID)

CDC is soliciting nominations for possible membership on the BSC, CCID. This board provides advice and guidance to the Secretary, Department of Health and Human Services (HHS), the Director, CDC, and the Director, CCID, concerning strategies and goals for the programs and research within the national centers; shall conduct peer-review of scientific programs; and monitor the overall strategic direction and focus of the national centers. The board shall also monitor program organization and resources for infectious disease prevention and control.

Nominations are being sought for individuals who have the expertise and qualifications necessary to contribute to the accomplishment of the board's objectives. Nominees will be selected by the Secretary, HHS, or designee, from authorities knowledgeable in the fields relevant to the issues addressed by the CCID and related disciplines, including: Epidemiology; microbiology; bacteriology; virology; parasitology; mycology; immunology; public health; entomology; bioterrorism threats; clinical medicine; ecology; and from the general public. Federal employees will not be considered. Members may be invited to serve for terms of up to four years.

Consideration is given to representation from diverse geographic areas, both genders, ethnic and minority groups, and the disabled. Nominees must be U.S. citizens.

The following information must be submitted for each candidate: Name, affiliation, address, telephone number, e-mail address, and current curriculum vitae.

Nominations should be accompanied with a letter of recommendation stating the qualifications of the nominee and postmarked by March 20, 2009 to: Harriette Lynch, Coordinating Center for Infectious Diseases, Office of the Director, CDC, 1600 Clifton Road, NE., Mailstop E–77, Atlanta, Georgia 30333, Telephone (404) 498–2726.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: February 25, 2009.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. E9–4475 Filed 3–2–09; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2008–N–0606]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Export of Food and Drug Administration Regulated Products: Export Certificates

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by April 2, 2009.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0498. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Export of Food and Drug Administration Regulated Products: Export Certificates (OMB Control Number 0910–0498)—Extension**

In April 1996 a law entitled ''The FDA Export Reform & Enhancement Act of 1996'' (FDAERA) amended sections 801(e) and 802 of the act (21 U.S.C. 381(e) and 382). It was designed to ease restrictions on exportation of unapproved pharmaceuticals, biologics, and devices regulated by FDA. Section 801(e)(4) of the FDAERA provides that persons exporting certain FDA-regulated products may request FDA to certify that the products meet the requirements of 801(e) or 802 or other requirements of the act. This section of the law requires FDA to issue certification within 20 days of receipt of the request and to charge firms up to $175.00 for the certifications.

This new section of the act authorizes FDA to issue export certificates for regulated pharmaceuticals, biologics, and devices that are legally marketed in the United States, as well as for these same products that are not legally marketed but are acceptable to the importing country, as specified in sections 801(e) and 802 of the act. FDA has developed five types of certificates that satisfy the requirements of section 801(e)(4)(B) of the act: (1) Certificates to Foreign Governments, (2) Certificates of Exportability, (3) Certificates of a Pharmaceutical Product, (4) Non-Clinical Research Use Only Certificates, and (5) Certificates of Free Sale. Table 1 of this document lists the different certificates and details their use:

TABLE 1.

| Type of Certificate | Use |
|---|---|
| ''Supplementary Information Certificate to Foreign Government Requests''<br>''Exporter's Certification Statement *Certificate to Foreign Government*''<br>''Exporter's Certification Statement *Certificate to Foreign Government* (For Human Tissue Intended for Transplantation)'' | For the export of products legally marketed in the United States |
| ''Supplementary Information Certificate of Exportability Requests''<br>''Exporter's Certification Statement *Certificate of Exportability*'' | For the export of products not approved for marketing in the United States (unapproved products) that meet the requirements of sections 801(e) or 802 of the act |
| ''Supplementary Information Certificate of a Pharmaceutical Product''<br>''Exporter's Certification Statement *Certificate of a Pharmaceutical Product*'' | Conforms to the format established by the World Health Organization and is intended for use by the importing country when the product in question is under consideration for a product license that will authorize its importation and sale or for renewal, extension, amending, or reviewing a license |
| ''Supplementary Information Non-Clinical Research Use Only Certificate''<br>''Exporter's Certification Statement *Non-Clinical Research Use Only*'' | For the export of a non-clinical research use only product, material, or component that is not intended for human use which may be marketed in, and legally exported from the United States under the act |
| Certificates of Free Sale | For food, cosmetic products, and dietary supplements that may be legally marketed in the United States |

FDA will continue to rely on self-certification by manufacturers for the first three types of certificates listed in table 1 of this document. Manufacturers are requested to self-certify that they are in compliance with all applicable requirements of the act, not only at the time that they submit their request to the appropriate center, but also at the time that they submit the certification to the foreign government.

The appropriate FDA centers will review product information submitted by firms in support of their certificate and any suspected case of fraud will be referred to FDA's Office of Criminal Investigations for follow-up. Making or submitting to FDA false statements on any documents may constitute violations of 18 U.S.C. 1001, with penalties including up to $250,000 in fines and up to 5 years imprisonment.

In the **Federal Register** of December 17, 2008 (73 FR 76655), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

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

| FDA Center | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| Center for Biologics Evaluation and Research | 1,501 | 1 | 1,501 | 1 | 1,501 |
| Center for Drug Evaluation and Research | 7,046 | 1 | 7,046 | 1 | 7,046 |
| Center for Devices and Radiological Health | 6,091 | 1 | 6,091 | 2 | 12,182 |
| Center for Veterinary Medicine | 664 | 1 | 664 | 1 | 664 |

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