Estimated Total Annual Burden Hours: 520.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF. E-mail address: *Katherine_T._Astrich@omb.eop.gov.*

Dated: June 26, 2006.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 06–5980 Filed 7–3–06; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004E–0396]

Determination of Regulatory Review Period for Purposes of Patent Extension; TAXUS EXPRESS Paclitaxel-Eluting Coronary Stent System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for TAXUS EXPRESS Paclitaxel-Eluting Coronary Stent System 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.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

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 TAXUS EXPRESS Paclitaxel-Eluting Coronary Stent System. TAXUS EXPRESS Paclitaxel-Eluting Coronary Stent System is indicated for improving luminal diameter for the treatment of *de novo* lesions ≤28 mm in length in native coronary arteries ≥2.5 to ≤3.75 mm in diameter. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for TAXUS EXPRESS Paclitaxel-Eluting Coronary Stent System (U.S. Patent No. 5,716,981) from Angiotech Phamaceuticals, 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 February 24, 2006, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of TAXUS EXPRESS Paclitaxel-Eluting Coronary Stent System 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 TAXUS EXPRESS Paclitaxel-Eluting Coronary Stent System is 716 days. Of this time, 456 days occurred during the testing phase of the regulatory review period, while 260 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 involving this device became effective*: March 21, 2002. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) for human tests to begin became effective on October 25, 2001. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on March 21, 2002, which represents the IDE effective date.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: June 19, 2003. The applicant claims February 25, 2003, as the date the premarket approval application (PMA) for TAXUS EXPRESS Paclitaxel-Eluting Coronary Stent System (PMA P030025) was initially submitted. However, FDA records indicate that PMA P030025 was submitted in modules and was not substantially complete until the final submission of clinical data on June 19, 2003.

3. *The date the application was approved*: March 4, 2004. FDA has verified the applicant's claim that PMA P030025 was approved on March 4, 2004.

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 807 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 September 5, 2006. 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 January 2, 2006. 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: June 13, 2006.

Jane A. Axelrad,

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

[FR Doc. E6–10408 Filed 7–3–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0065]

Emerging Clostridial Disease; Public Workshop; Reopening of the Administrative Record

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments; reopening of the administrative record.

SUMMARY: The Food and Drug Administration (FDA) is reopening until July 31, 2006, the administrative record to accept comments concerning the public workshop entitled ''Emerging Clostridial Disease,'' as the administrative record officially closed on June 15, 2006.

DATES: Submit written or electronic comments by July 31, 2006.

ADDRESSES: Submit written comments 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.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Lee Lemley, Center for Drug Evaluation and Research (HFD–006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5392.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 14, 2006 (71 FR 7778), FDA published a notice announcing a public workshop entitled ''Emerging Clostridial Disease,'' to be held on May 11, 2006. This workshop was developed in response to reports of morbidity and mortality associated with *Clostridium sordellii* (*C. sordellii*) and *Clostridium difficile* (*C. difficile*). These reports include cases and clusters of *C. sordellii* toxic shock syndrome following treatment with mifepristone, *C. sordellii* sepsis associated with tissue grafts, and rapidly fatal toxin-medicated cases of community acquired *C. difficile* infection. The goal of the workshop was to bring together scientific and public health experts to develop a draft research agenda. Additionally, the goals were to identify research needs and priorities that will enable rapid progress in detecting cases and conducting surveillance of disease and organisms. Interested persons were asked to submit written comments by June 15, 2006. In the interest of allowing additional comments to be received, FDA has decided to reopen the comment period until July 31, 2006.

Interested persons may, on or before July 31, 2006, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this public workshop. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments should 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.

Dated: June 28, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–10409 Filed 7–3–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Exxon Valdez Oil Spill Trustee Council; Request for Nominations

AGENCY: Office of the Secretary, Interior.

ACTION: Notice.

SUMMARY: The Exxon Valdez Oil Spill Trustee Council is soliciting nominations for the Public Advisory Committee, which advises the Trustee Council on decisions related to the planning, evaluation, and conduct of injury assessment, restoration, long-term monitoring, and research activities using funds obtained as part of the civil settlement pursuant to the T/V Exxon Valdez oil spill of 1989. Public Advisory Committee members will be selected to serve a 24-month term beginning in October 2006.

DATES: All nominations should be received on or before August 4, 2006.

ADDRESSES: Nominations should be sent to Executive Director, Exxon Valdez Oil Spill Trustee Council, 441 West 5th Avenue, Suite 500, Anchorage, Alaska 99501–2340 or by email to PAC Nominations, Executive Director, c/o Cherri Womac, *cherri_womac@evostc.state.ak.us*.

FOR FURTHER INFORMATION CONTACT: Douglas Mutter, Designated Federal Officer, Department of the Interior, Office of Environmental Policy and Compliance, 1689 ''C'' Street, Suite 119, Anchorage, Alaska, 99501, 907–271–5011; or Cherri Womac, Exxon Valdez Oil Spill Trustee Council, 441 West 5th Avenue, Suite 500, Anchorage, Alaska, 99501–2340, 907–278–8012 or 800–478–7745. A copy of the charter for the Public Advisory Committee is available upon request.

SUPPLEMENTARY INFORMATION: The Public Advisory Committee was created by Paragraph V.A.4 of the Memorandum of Agreement and Consent Decree entered into by the United States of America and the State of Alaska on August 27, 1991, and approved by the United States District Court for the District of Alaska in settlement of *United States of America* v. *State of Alaska*, Civil Action No. A91–081 CV. The Public Advisory Committee was created to advise the Trustee Council on matters relating to decisions on injury assessment, restoration activities or other use of natural resources damage recoveries obtained by the governments.

The Trustee Council consists of representatives of the State of Alaska Attorney General; Commissioner of the Alaska Department of Fish and Game; Commissioner of the Alaska Department of Environmental Conservation; the Secretary of the Interior; the Secretary of Agriculture; and the Administrator of the National Oceanic and Atmospheric Administration, U.S. Department of Commerce. Appointment to the Public Advisory Committee will be made by the Secretary of the Interior with unanimous approval of the Trustees.

The Public Advisory Committee consists of 15 members representing the