which have public health responsibilities for tuberculosis drug susceptibility testing and approval by their national tuberculosis program. While the overall number of cases of TB in the U.S. has decreased, rates still remain high among foreign-born persons, prisoners, homeless populations, and individuals infected with HIV in major metropolitan areas. The rate of TB cases detected in foreign-born persons has been reported to be almost nine times higher than the rate among the U.S. born population. CDC's goal to eliminate TB will be virtually impossible without considerable effort in assisting heavy disease burden countries in the reduction of tuberculosis. The M. tuberculosis/NTM program supports this role by monitoring the level of performance and practices among laboratories performing M. tuberculosis susceptibility within the U.S. as well as internationally to ensure high-quality laboratory testing, resulting in accurate and reliable results.

Information collected in this program will include the susceptibility test results of primary and secondary drugs, concentrations, and test methods performed by laboratories on a set of challenge isolates sent twice yearly.

A portion of the response instrument will collect demographic data such as laboratory type and the number of tests performed annually. By providing an evaluation program to assess the ability of the laboratories to test for drug resistant M. tuberculosis and selected strains of NTM, laboratories will also have a self-assessment tool to aid in maximizing their skills in susceptibility testing. Information obtained from laboratories on susceptibility testing practices and procedures will assist with determining variables related to good performance, with assessing areas for training and with developing practice standards. There is no cost to respondents.

Respondents	Number of respondents	Number of responses per respondenst	Average Burden per response (in hours)	Total burden (in hours)
XXXX	165	30	30/60	82.5
YYYY	165	30	30/60	82.5
Total				165

Dated: March 12, 2003.

Thomas Bartenfeld,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 03–6872 Filed 3–21–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Occupational Safety and Health Research, SOH Conflict Review, Program Announcement #99–143

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Occupational Safety and Health Research, SOH Conflict Review, Program Announcement #99–143.

Times and Dates: 1 p.m.–1:30 p.m., April 8, 2003 (open). 1:30 p.m.–5 p.m., April 8, 2003 (closed).

Place: Executive Park, Building 24, Conference Room 1525, Atlanta, GA 30329.

Phone: 404.498.2508.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c) (4) and (6), title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to PA# 99–143.

Contact Person for More Information: Gwendolyn Cattledge, Ph.D., Scientific Review Administrator, National Institute Occupational for Safety and Health, CDC, 1600 Clifton Rd., NE., MS–E74, Atlanta, GA 30333, Telephone (404) 498–2586.

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 the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: March 19, 2003.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 03–7002 Filed 3–20–03; 1:21 pm]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02E–0149]

Determination of Regulatory Review Period for Purposes of Patent Extension; GENESIS NEUROSTIMULATION SYSTEM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for GENESIS NEUROSTIMULATION 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 Dockets Management Branch (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: Claudia Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3460.

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 GENESIS NEUROSTIMULATION SYSTEM. GENESIS NEUROSTIMULATION SYSTEM is indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome, intractable low back pain, and leg pain. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for GENESIS NEUROSTIMULATION SYSTEM (U.S. Patent No. 4,793,353) from Advanced Neuromodulation Systems, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 31, 2002, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of GENESIS NEUROSTIMULATION 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 GENESIS NEUROSTIMULATION SYSTEM is 469 days. Of this time, 292 days occurred during the testing phase of the regulatory review period, while 177 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation involving this device was begun*: August 11, 2000. 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 June 16, 1999. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on August 11, 2000, 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)*: May 29, 2001. The applicant claims April 3, 2001, as the date the premarket approval application (PMA) for GENESIS NEUROSTIMULATION SYSTEM (PMA P010032) was initially submitted. However, FDA records indicate that PMA P010032 was submitted on May 29, 2001.

3. *The date the application was approved*: November 21, 2001. FDA has verified the applicant's claim that PMA P010032 was approved on November 21, 2001.

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 840 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments and ask for a redetermination by May 23, 2003. 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 September 22, 2003. 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 Dockets Management Branch. Three copies of any information are to be submitted, except that individuals may submit one copy identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 7, 2003.

Jane A. Axelrad,

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

[FR Doc. 03–6892 Filed 3–21–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Filing of Annual Report of Federal Advisory Committee

Notice is hereby given that pursuant to section 13 of Public Law 92–463, the fiscal year 2002 annual report for the following Health Resources and Services Administration's Federal advisory committee has been filed with the Library of Congress: Maternal and Child Health Research Grants Review Committee.

Copies are available to the public for inspection at the Library of Congress, Newspaper and Current Periodical Reading Room in the James Madison Memorial Building, Room LM–133 (entrance on Independence Avenue, between First and Second Streets, SE., Washington, DC).

Copies may be obtained from: Kishena C. Wadhwani, Ph.D., Executive Secretary, Maternal and Child Health Research Grants Review Committee, Parklawn Building, Room 18A–55, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone 301–443–2340.

Dated: March 17, 2003.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 03–6858 Filed 3–21–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

OIG Compliance Program Guidance for Ambulance Suppliers

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This Federal Register notice sets forth the recently issued Compliance Program Guidance for Ambulance Suppliers developed by the Office of Inspector General (OIG). The OIG has previously developed and published voluntary compliance program guidance focused on several different areas of the health care