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