will be asked to leave your name, address, and telephone number and will need to refer to NIOSH Announcement 756. You will receive a complete program description, information on application procedures, and application forms. CDC will not send application kits by facsimile or express mail. Please refer to NIOSH Announcement Number 756 when requesting information and submitting an application.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Victoria Sepe, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Mailstop E–13, Room 321, 255 East Paces Ferry Road, NE., Atlanta, GA 30305, telephone (404) 842–6804, Internet: vxw1@cdc.gov.

Programmatic technical assistance may be obtained from Dr. Lee Petsonk, Division of Respiratory Disease Studies, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC), 1095 Willowdale Road, Mailstop 240, Morgantown, WV 26505, telephone (304) 285–5714, Internet address: elp2@cdc.gov.

This and other CDC announcements are available through the CDC homepage on the Internet. The address for the CDC homepage is: http://www.cdc.gov.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report, Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

National Occupational Research Agenda: Copies of this publication may be obtained from the National Institute for Occupational Safety and Health, Publications Office, 4676 Columbia Parkway, Cincinnati, OH 45226–1998 or telephone 1–800–356–4674, and is available through the NIOSH Home Page: http://www.cdc.gov/niosh/nora.html.

Dated: June 11, 1997.

Diane D. Porter,

Acting Director, National Institute for Occupational Safety and Health Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–15888 Filed 6–17–97; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Citizens Advisory Committee on Public Health Service (PHS) Activities and Research at Department of Energy (DOE) Sites: Idaho National Engineering Laboratory Health Effects Subcommittee: Time Change

Federal Register *CITATION OF PREVIOUS ANNOUNCEMENT:* 62 FR 30870—dated June 5, 1997.

SUMMARY: Notice is given that the meeting time for the Citizens Advisory Committee on PHS Activities and Research at DOE Sites: Idaho National Engineering Laboratory (INEL) Health Effects Subcommittee, of the Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control and Prevention (CDC) has changed. The meeting dates, place, status, and purpose, announced in the original notice remain unchanged.

Original Times and Dates: 8:30 a.m.–5 p.m., June 26, 1997. 8:30 a.m.–5 p.m., June 27, 1997.

New Times and Dates: 8:30 a.m.–5 p.m., June 26, 1997. 6 p.m.–7 p.m., June 26, 1997. 8:30 a.m.–5 p.m., June 27, 1997.

CONTACT PERSONS FOR MORE INFORMATION: Arthur J. Robinson, Jr., or Nadine Dickerson, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, (F–35), Atlanta, Georgia 30341–3724, telephone 770/488–7040, FAX 770/488–7044.

Dated: June 12, 1997.

Nancy C. Hirsch,

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

[FR Doc. 97–15916 Filed 6–17–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0184]

Gen-Probe®, Inc.; Premarket Approval of Gen-Probe® Amplified Mycobacterium Tuberculosis Direct Test

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Gen-Probe®, Inc., San Diego, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Gen-Probe® Amplified *Mycobacterium tuberculosis* Direct Test (MTD). After reviewing the recommendation of the Microbiology Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter on December 15, 1995, of the approval of the application.

DATES: Petitions for administrative review by July 18, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review, to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Sharon L. Hansen, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–2096.

SUPPLEMENTARY INFORMATION: On July 11, 1994, Gen-Probe®, Inc., San Diego, CA, 92121, submitted to CDRH an application for premarket approval of the Gen-Probe® Amplified MTD. The device is a target-amplified nucleic acid probe test for the in vitro diagnostic detection of *M. tuberculosis* complex rRNA in acid fast bacilli (AFB) smear positive concentrated sediments prepared from sputum (induced or expectorated), bronchial specimens (e.g., bronchoalveolar lavages or bronchial aspirates), or tracheal aspirates. The MTD test is intended for use as an adjunctive test for evaluating AFB smear positive concentrated sediments prepared using NALC–NaOH digestion-decontamination of respiratory specimens from untreated patients suspected of having tuberculosis. Patients who have received no anti-tuberculous therapy, less than 7 days of such therapy, or have not received such therapy in the last 12 months may be evaluated with this test. The MTD test should be performed only in laboratories proficient in the culture and identification of *M. Tuberculosis* (Level II and III, or extent 3 and 4). The MTD should always be performed in conjunction with a mycobacterial culture.

On May 2, 1995, the Microbiology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On December 15, 1995, CDRH approved the