In recent years, regulatory authorities and industry associations have undertaken many important initiatives to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization. FDA is committed to seeking scientifically based harmonized technical procedures for medical device regulation. One of the goals of harmonization is to identify similarities and differences in technical requirements for medical devices, increase the similarities, and reduce the differences. The GHTF was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives.

The GHTF is concerned with harmonization among three regions: the European Union, Asia-Pacific, and North America. The members of the GHTF are the European Union, Australia, Japan, Canada, and the United States. The GHTF Steering Committee is composed of four regulatory and four industry representatives from each region for a total of 12 regulatory and 12 industry representatives. The secretariat rotates from one region to another every 3 years. The Therapeutic Goods Administration of Australia currently serves as the secretariat for GHTF. Health Canada previously served as the secretariat. The Ministry of Health and Welfare of Japan will serve as the next secretariat.

GHTF study groups develop guidance documents on device regulation. There are currently four study groups: Study Group 1—premarket issues; Study Group 2—postmarket vigilance; Study Group 3—quality systems; and Study Group 4—auditing of quality systems.

The GHTF process is intended to achieve harmonization of the technical requirements for approval or clearance of medical devices, quality system requirements, procedures for auditing quality systems, and postmarket vigilance in the three regions. Information about the GHTF, its structure, proposed and final study group guidance documents, and the upcoming conference in Barcelona, Spain, can be found on the Internet at http://www.ghtf.org.

II. Issues To Be Discussed at the Public Meeting

The issues to be discussed include the following: (1) GHTF overview and procedures, (2) overview of GHTF Study Group work, (3) medical device nomenclature, and (4) possibilities for new topics.

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Oral presentations from the public will be scheduled. Time allotted for oral presentations may be limited to 10 minutes. Anyone desiring to make an oral presentation should notify the contact person by September 20, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the name and address, phone number, fax and e-mail of the proposed participant, and an indication of the approximate time requested to make the presentation.

The agenda for the public meeting will be available on September 17, 2001, at the Dockets Management Branch (address above) under Docket No. 01N–0384.

Transcripts: A transcript of the meeting will be posted on the Internet at: http://www.fda.gov/ohrms/dockets/dockets/docwhatsnew.htm under Docket No. 01N–0384. A transcript of the meeting also may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: September 6, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–22941 Filed 9–12–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel Phase II (SBIR)—Internet-Based Tools to Enhance Use of Online Health Resources.

Date: September 13, 2001.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute, Executive Plaza North Building, Conference Room C, 6130 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Kirt Vener, PhD, Branch Chief, Special Review and Resources Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6166 Executive Boulevard, Room 8061, Bethesda, MD 20892, (301) 496–7174.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: September 7, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–23010 Filed 9–12–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of person privacy.