Specialist identified in the Where to Obtain Additional Information of this announcement.'' and change to ''On or before October 10, 2001, submit the application to the Grants Management Specialist identified in the Where to Obtain Additional Information of this announcement.''

Dated: September 7, 2001.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 01–22976 Filed 9–12–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Center for Medicare and Medicaid Services

[Document Identifier: CMS–R–13]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services, DHHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Conditions of Coverage for Organ Procurement Organizations (OPOs) and Supporting Regulations in 42 CFR, Section 486.301–.325; *Form No.:* CMS–R–13 (OMB# 0938–0688); *Use:* OPOs are required to submit accurate data to CMS concerning population and information on donors and organs on an annual basis in order to assure maximum effectiveness in the procurement and distribution of organs.; *Frequency:* Annually; *Affected Public:* Not-for-profit institutions; *Number of Respondents:* 59; *Total Annual Responses:* 59; *Total Annual Hours:* 1.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at *http://www.hcfa.gov/regs/prdact95.htm,* or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to *Paperwork@hcfa.gov,* or call the Reports Clearance Office on (410) 786–1326, Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards, Attention: Melissa Musotto, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: September 4, 2001.

John P. Burke III,

CMS Reports Clearance Officer, CMS Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards.

[FR Doc. 01–22951 Filed 9–12–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0384]

Preparation for Global Harmonization Task Force Conference in Barcelona, Spain, Including a Discussion of Guidance Proposed for Comment and Currently Under Development and Possibilities for New Topics; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled ''Preparation for Global Harmonization Task Force Conference in Barcelona, Spain, Including a Discussion of Guidance Proposed for Comment and Currently Under Development and Possibilities for New Topics.'' The purpose of this meeting is to solicit information and receive comments on FDA's future participation in the Global Harmonization Task Force (GHTF) as well as the upcoming meetings in Barcelona, Spain. The topics to be discussed are an overview of GHTF, guidance proposed for comment and currently under development, and possibilities for new topics. This meeting is being held to solicit public input prior to the next meeting of the GHTF Steering Committee and Study Groups in Barcelona, Spain, from October 11 to 16, 2001, at which discussion of the guidance proposed for comment and under development and possible new topics will be continued.

Comments: Submit written comments 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. Comments are to be identified with the docket number found in brackets in the heading of this document.

Date and Time: The public meeting will be held on October 1, 2001, from 1:30 p.m. to 4:30 p.m.

Location: The public meeting will be held at 5630 Fishers Lane, rm. 1056, Rockville, MD.

Contact: Kimberly Topper, Center for Drug Evaluation and Research, Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20852, 301–827–7001, FAX 301–827–6801, or e-mail: Topperk@cder.fda.gov.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm or organization name, address, telephone, and fax number), and written material and requests to make oral presentations to the contact person by September 26, 2001.

If you need special accommodations due to a disability, please contact Kimberly Topper at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

I. Background

The GHTF was established in 1992 as a joint regulatory/industry project to encourage convergence in regulatory practices related to ensuring the safety, effectiveness/performance and quality of medical devices; promote technological innovation; and facilitate international trade. The GHTF works to achieve these objectives by disseminating guidance documents on basic regulatory practices. These documents, which are developed by four different GHTF Study Groups, can be adopted/implemented by member national regulatory authorities. Other national regulatory authorities that are not GHTF members also are encouraged to adopt and implement GHTF guidance documents.

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.