

ensure their adequate consideration in preparation of the final document by February 11, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of "Guidance for FDA: The Leveraging Handbook, An Agency Resource for Effective Collaborations" dated November 2001 to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the document 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: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Guidance for FDA Staff: The Leveraging Handbook, An Agency Resource for Effective Collaborations" dated November 2001. "Leveraging", as used by FDA, describes formal or informal relationships or agreements with others outside FDA that enhance the agency's ability to meet its public health mission. Leveraged collaborations between FDA and non-FDA partners, such as industry, academia, consumer groups, scientific experts, public health providers, States, and other government agencies, are not new to the agency. For many years, FDA has used collaborations to accomplish a wide variety of tasks related to fulfilling its public health mission. FDA is careful to structure its collaborations so that the agency's regulatory independence, impartiality, and integrity are preserved. Successful collaborations used by FDA and its partners range in size and complexity from simple daylong

workshops and training sessions to the creation of cooperatively administered centers that provide critical product-related safety information and expertise, i.e., the National Center for Food Safety and Technology, the Joint Initiative for Food Safety and Nutrition, and the Product Quality Research Institute. Other collaborations involve conducting research to improve the safety, efficacy, purity, or potency of regulated products and convening experts to evaluate emerging public health issues and to recommend actions that should be taken to address the issues.

FDA held two public meetings that were announced in the **Federal Register** to discuss ways in which FDA could improve and increase collaborations with outside organizations (65 FR 8365, February 18, 2000). The meetings were held on March 23, 2000, at Stanford University, and on April 12, 2000, at Duke University. More than 300 people attended the meetings and more than 25 leveraging proposals were presented to the agency. FDA is currently reviewing the proposals. To review the transcripts of the meetings, you can visit the FDA Dockets Management Branch Web site at <http://www.fda.gov/ohrms/dockets/dockets/00n0001/00n0001.htm>.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance document represents the agency's current thinking on the formation and implementation of leveraged collaborations between FDA and outside organizations. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Comments

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this draft guidance document. Submit written comments to ensure adequate consideration in preparation of the final document by February 11, 2002. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets

Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance document at either <http://www.fda.gov/oc/leveraging/handbook.html> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: August 31, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01-28386 Filed 11-9-01; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Council on Graduate Medical Education; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), announcement is made of the following National Advisory body scheduled to meet during the month of December 2001:

Name: Council on Graduate Medical Education (COGME).

Date and Time: December 5, 2001, 8:30 a.m.-4:30 p.m., December 6, 2001, 8:30 a.m.-12 p.m.

Place: Holiday Inn, Capitol, Columbia Ballroom, 550 C Street, SW., Washington, DC 20024.

The meeting is open to the public.

Agenda: The agenda for the first day, December 5, will include: Welcome and opening comments from the Acting Administrator, Health Resources and Services Administration; the Associate Administrator for Health Professions; and the Acting Executive Secretary of COGME. There will be a panel of speakers on the topic of "Models of Health Care Delivery." The afternoon agenda includes a presentation on "Substitutability in the Physician Workforce." The Council's three workgroups will convene. They are: Workgroup on Diversity, Workgroup on Graduate Medical Education Financing, and Workgroup on Workforce.

The agenda for the second day, December 6, will include reports from the three workgroup chairs. Work will continue on COGME's Final Report. There will be a discussion on plans for future work and new business.

Anyone requiring information regarding the meeting should contact Stanford M. Bastacky, D.M.D., M.H.S.A., Acting Executive Secretary, Council on Graduate Medical Education, Division of Medicine and Dentistry, Bureau of Health Professions, Room 9A-27, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Telephone (301) 443-6326,

Agenda items are subject to change as priorities dictate.

Dated: November 6, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 01-28259 Filed 11-9-01; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of 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 meeting of the National Cancer Advisory Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

A portion of the meeting will be closed to the public in accordance with the provisions set forth in section 552b(6), as amended. The discussions could disclose personal information concerning NCI Staff and/or its contractors, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Advisory Board.

Dates: December 4-5, 2001.

Open: December 4, 2001, 8:45 a.m. to 4 p.m.

Agenda: Program reports and presentations; Business of the Board.

Place: National Cancer Institute, 900 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Dr. Marvin R. Kalt, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892-8327, (301) 496-5147.

Name of Committee: National Cancer Advisory Board.

Closed: December 4, 2001, 4 p.m. to Recess.

Agenda: Review intramural program site visit outcomes; Discussion of confidential personnel issues.

Place: National Cancer Institute, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Dr. Marvin R. Kalt, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116

Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892-8327, (301) 496-5147.

Name of Committee: National Cancer Advisory Board.

Open: December 5, 2001, 8:30 a.m. to Adjournment.

Agenda: Program reports and presentations; Business of the Board.

Place: National Cancer Institute, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Dr. Marvin R. Kalt, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892-8327, (301) 496-5147.

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.

Information is also available on the Institute's homepage: deainfo.nci.nih.gov/odvisory/ncab.htm, where an agenda and any additional information for the meeting will be posted when available.

(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: November 2, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01-28317 Filed 11-9-01; 8:45 am]

BILLING CODE 4140-01-M

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 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 personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Chemoprevention of Tobacco-Related Cancers in Former Smokers.

Date: December 6, 2001.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute, 6130 Executive Boulevard., Conference Room J, Rockville, MD 20852.

Contact Person: Timothy C. Meeker, MD, Scientific Review Administrator, Special Referral and Resources Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 8088, Rockville, MD 20852, 301/594-1279.

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: November 2, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01-28318 Filed 11-9-01; 8:45 am]

BILLING CODE 4140-01-M

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 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 personal privacy.