Small Business Representative Program, which are, in part, to respond to industry inquiries, develop educational materials, and sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA’s guidance. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), as outreach activities by Government Agencies to small businesses.

The goal of this public workshop is to present information that will enable regulated industry to better comply with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), and to better understand FDA’s food defense guidance, especially in light of growing concerns about food protection. Information presented will be based on Agency position as articulated through regulation, guidance, and information previously made available to the public. Topics to be discussed at the workshop include the following:

- Food defense awareness and definitions,
- FDA food defense tools such as ALERT and Employees FIRST,
- Regulations mandated by the Bioterrorism Act,
- Food Defense Guidance from the Food Safety and Inspection Service,
- Investigating food-related incidents effectively,
- Physical plant security,
- Crisis management, and
- A food related emergency exercise bundle (FREE—B) tabletop exercise on food defense.

For more information, please visit http://www.fapc.biz/fooddefense2012.html. FDA expects that participation in this public workshop will provide regulated industry with greater understanding of the Agency’s regulatory and policy perspectives on food protection, increase compliance with FDA regulations, and heighten food defense awareness.


Leslie Kux,
Assistant Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings. The meetings 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 Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Hearing—Clinical Trials & Translational Research.

Date: October 12, 2012.
Time: 11:00 a.m. to 2:30 p.m.
Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Christine A. Livingston, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institutes of Health/NIDCD, 6120 Executive Blvd.—MSC 7180, Bethesda, MD 20892 (301) 496–8683, livingsc@mail.nih.gov.

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Vestibular—Clinical Trials.

Date: October 23, 2012.
Time: 11:00 a.m. to 2:00 p.m.
Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Christine A. Livingston, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institutes of Health/NIDCD, 6120 Executive Blvd.—MSC 7180, Bethesda, MD 20892 (301) 496–8683, livingsc@mail.nih.gov.

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Chemosensory Fellowship Application Review.

Date: October 24, 2012.
Time: 10:30 a.m. to 2:00 p.m.
Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Andrea B. Kelly, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institutes of Health/NIDCD, 6120 Executive Blvd.—MSC 7180, Rockville, MD 20892 (301) 496–8683, kellya2@nidcd.nih.gov.

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Auditory—CNS Stimulation & Prostheses Clinical Trials.

Date: October 25, 2012.
Time: 9:00 a.m. to 11:00 a.m.
Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Melanie J. Gray, Program Analyst, Office of Federal Advisory Committee Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute On Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; NIAAA AA–1 Member Conflict Applications.

Date: October 9, 2012.
Time: 2:00 p.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.

Place: NIAAA, Rockville, MD, (Telephone Conference Call).

Contact Person: Richard A Rippe, Ph.D., Scientific Review Officer, National Institute
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Cancer Institute Board of Scientific Advisors.

The meeting will be open to the public, 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 contact the National Cancer Institute's/Center's home page:

http://deainfo.nci.nih.gov/advisory/bsa/bsa.htm, where an agenda and any additional information for the meeting will be posted when available.

Name of Committee: National Cancer Institute Board of Scientific Advisors.

Date: November 5, 2012.

Time: 9 a.m. to 5 p.m.

Agenda: Report of the Director, NCI; Ongoing and New Business; Reports of Program Review Group(s); and Budget Presentation: Reports of Special Initiatives; RFA and RFP Concept Reviews; and Scientific Presentations.

Place: National Institutes of Health, Building 31, 31 Center Drive, 6th Floor, Conference Rm. 10, Bethesda, MD 20892.

Contact Person: Paulette S. Gray, Ph.D., Executive Secretary, Director, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Rm. 8001, Bethesda, M D 20892, 301–496–5147, grayp@mail.nih.gov.

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/Center's home page: http://deainfo.nci.nih.gov/advisory/bsa/bsa.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)

Carolyn A. Baum,
Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Projects for Assistance in Transition From Homelessness (PATH) Program Annual Report (OMB No. 0930–0205)—Revision

The Center for Mental Health Services awards grants each fiscal year to each of the States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands from allotments authorized under the PATH program established by Public Law 101–645, 42 U.S.C. 290cc–21 et seq., the Stewart B. McKinney Homeless Assistance Amendments Act of 1990 (section 521 et seq. of the Public Health Service (PHS) Act). Section 522 of the PHS Act requires that the grantee States and Territories must expend their payments under the Act solely for making grants to political subdivisions of the State, and to non-profit private entities (including community-based veterans’ organizations and other community organizations) for the purpose of providing services specified in the Act. Available funding is allotted in accordance with the formula provision of section 524 of the PHS Act.

This submission is for a revision of the current approval of the annual grantee reporting requirements. Section 528 of the PHS Act specifies that not later than January 31 of each fiscal year, a funded entity will prepare and submit a report in such form and containing such information as is determined necessary for securing a record and description of the purposes for which amounts received under section 521 were expended during the preceding fiscal year and of the recipients of such amounts and determining whether such amounts were expended in accordance with statutory provisions.

The proposed changes to the PATH Annual Report Survey are as follows:

1. Format

To create a PATH report that is easier to read, the formatting has been modified to be more table driven. In addition, the language has been made more concise. Although the online form and report is close in flow to the previous report, it is necessary to thoroughly read all reporting instructions to insure proper data entry.

2. Estimated Counts

The new PATH report does not include entry of estimated counts. Only actual counts should be entered.

3. Homelessness Management Information System (HMIS) Data Integration

The Data section of the report is expected to be propagated from the local HMIS when providers use HMIS. This includes client counts, services, referrals, and demographics. This data will be automatically aggregated from client-level data.

4. Demographic Responses

In order to facilitate integration of PATH data into HMIS, all data responses have been modified to fully align with valid HMIS responses. For example, the “Hispanic” response has been separated from “Race” and placed in “Ethnicity.”

5. Additional Data Items

The PATH report page tracks demographic data for persons contacted, as well as those enrolled. For services and referrals, in addition to gathering the number of enrolled persons receiving the service or referral, there is a total count of the number of times that particular service was provided or referral made.

6. Voluntary Outcome Measures

The data previously entered as voluntary outcome measures has now been moved to the referral section of the report and are no longer considered “voluntary.”

The estimated annual burden for these reporting requirements is summarized in the table below.