

representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of February 17, 2009 (74 FR 7447), FDA published a notice announcing the availability of a draft tripartite guidance entitled "Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 7: Dissolution Test General Chapter." The notice gave interested persons an opportunity to submit comments by April 20, 2009.

After consideration of the comments received and revisions to the guidance, a final draft guidance entitled "Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 7: Dissolution Test General Chapter" was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in October 2009.

The guidance provides the specific evaluation outcome from the ICH Q4B process for the Dissolution Test General Chapter harmonization proposal originating from the three-party PDG. This guidance is in the form of an annex to the core ICH Q4B guidance made available in the **Federal Register** of February 21, 2008 (73 FR 9575). When implemented, the annex will provide guidance for industry and regulators on the use of the specific pharmacopoeial texts evaluated by the ICH Q4B process. Following receipt of comments on the draft, no substantive changes were made to the annex.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).

The guidance represents the agency's current thinking on this topic. 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 requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.regulations.gov>, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Dated: March 31, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-7593 Filed 4-2-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Meeting

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

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.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and

evaluation of individual intramural programs and projects conducted by the National Institute on Aging, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIA.

Date: May 11–12, 2010.

Closed: May 11, 2010, 8 a.m. to 8:30 a.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Open: May 11, 2010, 8:30 a.m. to 12 p.m.

Agenda: Committee Discussion.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Closed: May 11, 2010, 12 p.m. to 1:15 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Open: May 11, 2010, 1:15 p.m. to 4:15 p.m.

Agenda: Committee Discussion.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Closed: May 11, 2010, 4:15 p.m. to 4:30 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Open: May 11, 2010, 4:30 p.m. to 5 p.m.

Agenda: Committee Discussion.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Closed: May 11, 2010, 5 p.m. to 6 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Closed: May 12, 2010, 8 a.m. to 9 a.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Open: May 12, 2010, 9 a.m. to 11:30 a.m.

Agenda: Committee Discussion.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview

Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Closed: May 12, 2010, 11:30 a.m. to 12:45 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Open: May 12, 2010, 12:45 p.m. to 3:45 p.m.

Agenda: Committee Discussion.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Closed: May 12, 2010, 3:45 p.m. to 5 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institute on Aging, Biomedical Research Center, 251 Bayview Boulevard, 3rd Floor Conference Room, Baltimore, MD 21224.

Contact Person: Michele K. Evans, MD, Acting Scientific Director, National Institute on Aging, 251 Bayview Boulevard, Suite 100, Room 04C221, Baltimore, MD 21224.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: March 31, 2010.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-7668 Filed 4-2-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Deafness and Other Communication Disorders Advisory Council.

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.

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 Deafness and Other Communication Disorders Advisory Council.

Date: May 14, 2010.

Closed: 8:30 a.m. to 10:15 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, Bethesda, MD 20892.

Open: 10:15 a.m. to 2:30 p.m.

Agenda: Staff reports on divisional, programmatic, and special activities.

Place: National Institutes of Health, Building 31, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Craig A. Jordan, PhD, Director, Division of Extramural Activities, NIDCD, NIH, Executive Plaza South, Room 400C, 6120 Executive Blvd., Bethesda, MD 20892-7180. 301-496-8693.

jordanc@nidcd.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.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: <http://www.nidcd.nih.gov/about/groups/ndcdac/>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: March 30, 2010.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-7671 Filed 4-2-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 materials, 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 of Mental Health Special Emphasis Panel; Child Interventions Review.

Date: April 14, 2010.

Time: 2:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Marina Broitman, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6153, MSC 9608, Bethesda, MD 20892-9608, 301-402-8152, *mbroitman@mail.nih.gov.*

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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: March 29, 2010.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-7675 Filed 4-2-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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 USC,