

will also participate in daily workshops with their industry counterparts, focusing on selective regulatory issues important to both CDER staff and industry. The primary objective of the daily workshops is to learn about the team approach to drug development, including drug discovery, preclinical evaluation, tracking mechanisms, and regulatory submission operations. The overall benefit to regulatory project managers will be exposure to project management, team techniques, and processes employed by the pharmaceutical industry. By participating in this program, the regulatory project manager will grow professionally by gaining a better understanding of industry processes and procedures

### III. Site Selection

All travel expenses associated with the site tours will be the responsibility of CDER; therefore, selection will be based on the availability of funds and resources for each fiscal year. Selection will also be based on firms having a favorable facility status as determined by FDA's Office of Regulatory Affairs District Offices in the firms' respective regions. Firms interested in offering a site tour or learning more about this training opportunity should respond by (see **DATES**) by submitting a proposed agenda to Beth Duvall-Miller (see **FOR FURTHER INFORMATION CONTACT**).

Dated: March 3, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## 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, Member Conflicts SEP.

*Date:* April 22, 2010.

*Time:* 12 p.m. to 2 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* NIAAA, 5635 Fishers, Rockville, MD 20852.

*Contact Person:* Lorraine Gunzerath, PhD, MBA, Scientific Review Officer, National Institute on Alcohol Abuse and Alcoholism, Office of Extramural Activities, Extramural Project Review Branch, 5635 Fishers Lane, Room 2121, Bethesda, MD 20892-9304, 301-443-2369. *lgunzera@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)

Dated: February 26, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Subcommittee on Procedures Reviews (SPR), Advisory Board on Radiation and Worker Health (ABRWH), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC), announces the following meeting for the aforementioned subcommittee:

*Time and Date:* 9:30 a.m.-5 p.m., March 23, 2010.

*Place:* Cincinnati Airport Marriott, 2395 Progress Drive, Hebron, Kentucky 41018. Telephone: (859) 334-4611, Fax: (859) 334-4619.

*Status:* Open to the public, but without a public comment period. To access by conference call dial the following information 1(866) 659-0537, Participant Pass Code 9933701.

*Background:* The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the compensation program. Key functions of the Advisory Board include

providing advice on the development of probability of causation guidelines that have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2011.

*Purpose:* The Advisory Board is charged with (a) Providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class. The Subcommittee on Procedures Reviews was established to aid the Advisory Board in carrying out its duty to advise the Secretary, HHS, on dose reconstruction. It is responsible for overseeing, tracking, and participating in the reviews of all procedures used in the dose reconstruction process by the NIOSH Office of Compensation Analysis and Support (OCAS) and its dose reconstruction contractor.

*Matters To Be Discussed:* The agenda for the Subcommittee meeting includes: the development of recommendations for an Advisory Board procedure for reviewing OCAS Program Evaluation Reports; and discussion of the following Oak Ridge Associated Universities & OCAS procedures: OTIB-013 ("Special External Dose Reconstruction Considerations for Mallinckrodt Workers"), OTIB-014 ("Rocky Flats Internal Dosimetry Co-Worker Extension"), OTIB-0029 ("Internal Dosimetry Coworker Data for Y-12"), OTIB-0049 ("Estimating Doses for Plutonium Strongly Retained in the Lung"), OTIB-0047 (External Radiation Monitoring at the Y-12 Facility During the 1948-1949 Period"), OTIB-0051 ("Effect of Threshold Energy and Angular Response of NTA Film on Missed Neutron Dose at the Oak Ridge Y-12 Facility"), OTIB-0054 ("Fission and Activation Product Assignment for Internal Dose-Related Gross Beta and Gross Gamma Analyses"), and OTIB-0070 ("Dose Reconstruction During Residual Radioactivity Periods at Atomic Weapons Employer Facilities"); and a continuation of the comment-resolution process for other dose reconstruction procedures under review by the Subcommittee.