

- Recalls—Globally;
 - GHTF Document on CAPA—
- Workshop;
- 510(k)—An Industry Perspective;
 - Interdependency of Postmarket
- Surveillance, Risk, and CAPA;
- Promotional Practices—Global;
 - Office of Compliance Initiatives;
 - U.S. Senate HELP Committee
- Keynote Dinner;
- Risk Management Across the
- Quality Systems—FDA Expectations and Implementation;
- Global Regulatory Strategy; and
 - FDA Inspectional Approach—Panel
- With Current FDA Investigators.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The conference helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The conference also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) by providing outreach activities by Government Agencies to small businesses.

Dated: February 15, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–4036 Filed 2–21–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0093]

Training Program for Regulatory Project Managers; Information Available to Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) is announcing the continuation of the Regulatory Project Management Site Tours and Regulatory Interaction Program (the Site Tours Program). The purpose of this document is to invite pharmaceutical companies interested in participating in this program to contact CDER.

DATES: Pharmaceutical companies may submit proposed agendas to the Agency by April 23, 2012.

FOR FURTHER INFORMATION CONTACT: Dan Brum, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4160, Silver Spring, MD 20993–0002, 301–796–0578, email: dan.brum@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

An important part of CDER's commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of the drug review process. To support this primary goal, CDER has initiated various training and development programs to promote high performance in its regulatory project management staff. CDER seeks to significantly enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing its training program to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide the following: (1) Firsthand exposure to industry's drug development processes and (2) a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

II. The Site Tours Program

In this program, over a 2- to 3-day period, small groups (five or less) of regulatory project managers, including a senior level regulatory project manager, can observe operations of pharmaceutical manufacturing and/or packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. Neither this tour nor any part of the program is intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but is meant rather to improve mutual understanding and to provide an avenue for open dialogue. During the Site Tours Program, regulatory project managers 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 submitting a proposed agenda to Dan Brum (see **DATES** and **FOR FURTHER INFORMATION CONTACT**).

Dated: February 14, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–4034 Filed 2–21–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute 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 Heart, Lung, and Blood Institute Special Emphasis Panel; Cardiothoracic Surgery Program.

Date: March 12, 2012.

Time: 11 a.m. to 1 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Chang Sook Kim, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7179, Bethesda, MD 20892–7924, 301–435–0287, carolko@mail.nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Translational Programs in Lung Diseases.

Date: March 14–15, 2012.

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

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Susan Wohler Sunnarborg, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National, Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7185, Bethesda, MD 20892, sunnarborgsw@nhlbi.nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Computer Generated Diet and Exercise Reminders Promoting Cardiovascular Health.

Date: March 14, 2012.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate contract proposals.

Place: Westin Alexandria, 400 Courthouse Square, Alexandria, VA 22314.

Contact Person: William J Johnson, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7178, Bethesda, MD 20892–7924, 301–435–0725, johnsonwj@nhlbi.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: February 15, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–4109 Filed 2–21–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Drug Discovery and Mechanisms of Antimicrobial Resistance Overflow.

Date: March 1–2, 2012.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Guangyong Ji, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3188, MSC 7808, Bethesda, MD 20892, 301–435–1146, jig@csr.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.

Name of Committee: AIDS and Related Research Integrated Review Group; HIV/AIDS Vaccines Study Section.

Date: March 9, 2012.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: The Seattle Westin, 1900 5th Avenue, Seattle, WA 98101.

Contact Person: Mary Clare Walker, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5208, MSC 7852, Bethesda, MD 20892, (301) 435–1165, walkermc@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: February 14, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–4101 Filed 2–21–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; 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 of Dental and Craniofacial Research Special Emphasis Panel; RFA DE12–004 & 005 Functional Restoration of Salivary Glands.

Date: March 8, 2012.

Time: 8 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn, 7301 Waverly St., Bethesda, MD 20814.

Contact Person: Marilyn Moore-Hoon, Ph.D., Scientific Review Officer Scientific Review Branch, National Institute of Dental and Craniofacial Research, 6701 Democracy Blvd., Rm. 676, Bethesda, MD 20892–4878, 301–594–4861, mooremar@nidcr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: February 14, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–4098 Filed 2–21–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research 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 of Dental and Craniofacial Research Special Emphasis Panel; Review of RFA DE 12–006 and –007 Oral Diseases in Medically Compromised Patients (R21, R01).

Date: March 13, 2012.

Time: 10 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Jonathan Horsford, Ph.D., Scientific Review Officer, Natl Inst of Dental and Craniofacial Research, National Institutes