

interested in collaborative research directed toward molecular strategies for vaccine and antiviral development, and animal models of viral hepatitis C. For more information, please contact Dr. T. Jake Liang at 301-496-1721, [jliliang@nih.gov](mailto:jliliang@nih.gov), or Ms. Patricia Lake at 301-594-6762, [lakep@mail.nih.gov](mailto:lakep@mail.nih.gov).

Dated: April 29, 2009.

**Richard U. Rodriguez,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0664]

#### Implementation of Post-Approval Studies for Medical Devices; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Implementation of Post-Approval Studies for Medical Devices." The purpose of the workshop is to facilitate discussion among FDA and other interested parties on issues related to the implementation of Post-Approval Studies for medical devices.

**Date and Time:** The workshop will be held on June 4, 2009, from 9 a.m. to 5 p.m. and June 5, 2009, from 9 a.m. to 12 p.m. Participants are encouraged to arrive early to ensure time for parking and security screening before the meeting. Security screening will begin at 8 a.m., and registration will begin at 8:30 a.m. Please pre-register by May 28, 2009, using the instructions in this document.

**Location:** The workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Silver Spring, MD 20993.

**Contact Persons:** Ellen Pinnow, Center for Devices and Radiological Health (HFZ-541), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240-276-2373, e-mail: [ellen.pinnow@fda.hhs.gov](mailto:ellen.pinnow@fda.hhs.gov); or Daniel Canos, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240-276-2369, [daniel.canos@fda.hhs.gov](mailto:daniel.canos@fda.hhs.gov).

**Registration:** E-mail your name, title, organization affiliation, address, and e-mail contact information to Stephanie

Zafonte at [SZafonte@s-3.com](mailto:SZafonte@s-3.com). There is no fee to attend the workshop, but attendees must register in advance. The registration process will be handled by Social and Scientific Systems, which has extensive experience in planning, executing, and organizing educational meetings. Although the facility is spacious, registration will be on a first-come, first-served basis. Non-U.S. citizens are subject to additional security screening, and they should register as soon as possible.

If you need special accommodations because of a disability, please contact Ellen Pinnow (see *Contact Persons*) at least 7 days before the public workshop.

#### SUPPLEMENTARY INFORMATION:

##### I. Why Are We Holding This Public Workshop?

The purpose of the public workshop is to facilitate discussion among FDA and other interested parties on issues related to the conduct of Post-Approval Studies for medical devices.

##### II. What Are the Topics We Intend To Address at the Public Workshop?

We hope to discuss a large number of issues at the workshop, including, but not limited to:

- Regulatory requirements for implementing a Post-Approval Study for medical devices;
- Challenges and successful strategies for the recruitment of participants for Post-Approval Studies;
- Challenges and successful strategies for the retention and compliance with follow-up requirements of participants for Post-Approval Studies;
- Using existing infrastructure (e.g., national registries) to facilitate Post-Approval Studies; Using innovative strategies to facilitate Post-Approval Studies;
- Clinical research organizations, industry, academia, and other clinical trial consultant's perspectives on all of the previous issues related to implementing Post-Approval Studies for medical devices.

##### III. Where Can I Find Out More About This Public Workshop?

Background information on the public workshop, registration information, the agenda, information about lodging, and other relevant information will be posted, as it becomes available, on the Internet at <http://www.fda.gov/cdrh/meetings.html>.

Dated: April 29, 2009.

**Daniel G. Schultz,**

*Director, Center for Devices and Radiological Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Allergy and Infectious Diseases; 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 of Allergy and Infectious Diseases Special Emphasis Panel; Unsolicited Multi-Project Application.

**Date:** May 22, 2009.

**Time:** 11 a.m. to 2 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817. (Telephone Conference Call).

**Contact Person:** Peter R Jackson, Ph.D., Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, NIH/NIAID/DHHS, 6700-B Rockledge Drive, MSC 7616 Room 2220, Bethesda, MD 20892-7616. 301-496-2550.

**Name of Committee:** National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Ancillary Studies in Immunomodulation Clinical Trials.

**Date:** May 29, 2009.

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

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817. (Telephone Conference Call).

**Contact Person:** Paul A. Amstad, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892-7616. 301-402-7098. [pamstad@niaid.nih.gov](mailto:pamstad@niaid.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: April 29, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

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