

purpose of the public workshop is to facilitate discussion among FDA and worldwide orthopedic registries that have orthopedic implant information and create a research network to advance the methodology and conduct of research related to orthopedic device performance.

Date and Time: The public workshop will be held on May 9, 2011, from 8 a.m. to 5:30 p.m.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, rm. 1503 (the Great Room), Silver Spring, MD 20993. Participants are encouraged to arrive early to ensure time for parking and security screening before the meeting.

Contacts:

For information regarding the public workshop and registration: Betty Jo Alfstad, Surgical Outcomes and Analysis, Kaiser Permanente, 3033 Bunker Hill Street, B30, San Diego, CA 92109, 858-581-8272, e-mail: Betty.Jo.Alfstad@kp.org;

Tamia Woodruff, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 307-796-6091, e-mail:

Tamia.Woodruff@fda.hhs.gov.

Registration: There is no fee to attend the public workshop, but attendees must register in advance. 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. Registration ends April 25, 2011. Onsite registration is not available. If registration reaches maximum capacity prior to April 25, 2011, FDA will post a notice closing workshop registration on FDA's Web site at <http://www.fda.gov/cdrh/meetings.html>.

To register for the public workshop, mail or e-mail your name, title, organization affiliation, address, phone number, and email address to Betty Jo Alfstad (see *Contacts*). Registrants will receive e-mail confirmation upon acceptance for their participation in the public workshop. If you need special accommodations due to a disability, please contact Tamia Woodruff (see *Contacts*) at least 7 days in advance of 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 international orthopedic registries and develop a research consortium (ICOR) that will advance the

methodology and conduct of studies for orthopedic medical devices. We are reaching out to registries that have relevant data and are interested in collaboration to establish a network that will work with FDA to determine the evidence gaps and questions, datasets and approaches for conducting robust analytic studies and improve our understanding of the performance of orthopedic devices.

II. Who is the target audience for this public workshop? Who should attend this public workshop?

This workshop is open to all interested parties. The target audience is comprised of data holders, researchers, and industry interested in advancing the infrastructure and methods for studying orthopedic medical devices.

III. What are the topics we intend to address at the public workshop?

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

- Regulatory science, clinical community, payers' and patients' needs that led to creation of ICOR.
- New methods for distributed network based collaborative studies.
- The opportunities for medical device outcomes research.

IV. 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 7, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 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 Neurological Disorders and Stroke Initial Review Group; Neurological Sciences and Disorders C.

Date: June 9-10, 2011.

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

Agenda: To review and evaluate grant applications.

Place: Lorien Hotel and Spa, 1600 King Street, Washington, DC 22314.

Contact Person: William C. Benzing, PhD, Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892, 301-496-0660, benzingw@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: April 6, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 the National Advisory Neurological Disorders and Stroke 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 materials,