

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; 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 Arthritis and Musculoskeletal and Skin Diseases 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 Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

Date: February 2, 2010.

Open: 8:30 a.m. to 2 p.m.

Agenda: To discuss administrative details relating to the Council's business and special reports.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

Closed: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

Contact Person: Susana Serrate-Sztejn, MD, Director, Division of Skin and Rheumatic Diseases, NIAMS/NIH, 6701 Democracy Blvd, Suite 800, Bethesda, MD 20892-4872. (301) 594-5032. szteins@mail.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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: December 18, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Medical Device Interoperability; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Center for Devices and Radiological Health, in co-sponsorship with Continua Health Alliance and the Center for Integration of Medicine & Innovative Technology (CIMIT) is announcing a public workshop entitled "Medical Device Interoperability." The purpose of the workshop is to facilitate discussion among FDA, industry, academia, professional societies, clinical investigators and other interested parties on issues related to safe and effective interoperable medical devices.

Dates and Times: The public workshop will be held on January 25 and 26, 2010, from 9 a.m. to 5 p.m. and on January 27, 2010, from 9 a.m. to 12 noon. 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.

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

Contact Persons: Sandy Weininger, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., WO62/rm. 4212, Silver Spring, MD 20993, 301-796-2582, sandy.weininger@fda.hhs.gov; or John Murray, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., WO66/rm. 2634, Silver Spring,

MD 20993, 301-796-5543, john.murray@fda.hhs.gov.

Registration: To register for the public workshop, please visit the following Web site: http://mdpnp.org/FDA_Interop_Workshop.php. There is a registration fee of \$500 to attend the public workshop to cover the expenses and attendees must register in advance. The registration process will be handled by Continua Health Alliance. In person, attendance is limited to 200 participants.

Registration may be limited to achieve balanced participation. Upon registering, you will receive a notice indicating that your registration has been received and is pending confirmation. You will receive an additional email within 1 week notifying you if your registration was accepted or declined. You may also register to attend the public workshop via Web cast for a reduced fee.

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 Susana Rosales (Susana.Rosales@fda.hhs.gov) 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 regarding the safety and effectiveness of interoperable 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 public workshop, including, but not limited to the following:

- What are the types of clinical scenarios that would make use of medical device interoperability?
- What are the issues associated with premarket and postmarket studies for interoperable medical devices?
- What tools (e.g., standards, guidances) are in place or need to be developed to assure safety and effectiveness of interoperable medical device systems? What issues should they address?
- What are the risks associated with medical device interoperability and "system of systems" composing medical devices?
- What are other issues relevant to assuring the safety and effectiveness of interoperable medical devices?