

Biomedical Engineering Society (BMES) is announcing a public conference entitled "Frontiers in Medical Devices: Innovations in Modeling and Simulation". The purpose of this conference is to provide a forum to discuss strategies to effectively utilize computational modeling and simulation in the development and evaluation of medical devices.

**Date and Time:** The conference will be held on May 18 through 20, 2015, from 8 a.m. to 6 p.m.

**Location:** The public conference will be held at the Marriott Inn and Conference Center, University of Maryland, 3501 University Blvd. East, Hyattsville, MD 20783.

**Contact Person:** Donna R. Lochner, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 3220, Silver Spring, MD 20993, 301-796-6309, [Donna.Lochner@fda.hhs.gov](mailto:Donna.Lochner@fda.hhs.gov).

**Registration:** To register for the public conference please visit FDA's Medical Devices News, Events, Workshops, and Conferences calendar at <http://www.bmes.org/meddevicesconference>. There is a registration fee to attend the public conference to cover the expenses, and attendees must register in advance. The fees vary depending upon membership status in BMES, and include BMES members (\$450), non-BMES members (includes 1 year BMES membership) (\$600), and Government rate (BMES memberships and meals are not included) (\$250). Students will be offered a discounted fee of \$300 (BMES member) or \$350 (non-BMES member) (includes 1 year BMES membership). A full listing of the registration fees can be found on the Web site listed. Although the facilities are spacious, registration will be on a first-come, first-served basis.

If you need special accommodations due to a disability, please contact Betse Lyons at [Betse@bmes.org](mailto:Betse@bmes.org) or 301-459-1999, 8201 Corporate Drive, Suite 1125, Landover, MD 20785-2224, FAX: 301-459-2444, no later than May 4, 2015.

To register for the public conference, please visit BMES Frontiers in Medical Devices registration page at <http://bmes.org/meddevicesregistration>. Those without Internet access should contact Betse Lyons at 301-459-1999 to register.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

The Center for Devices and Radiological Health (CDRH) believes that computer modeling and simulation (M&S) has the potential to substantially augment traditional models used to evaluate medical devices; *i.e.*, animal,

bench, and human models, and to accelerate and streamline the total product life cycle of a medical device. The use of computer models to simulate multiple use conditions and to visualize and display complex processes and data can revolutionize the way medical outcomes and medical devices are understood. Non-proprietary computer models could benchmark device performance, yet lack of access to biomedical data to construct the models and rigorous methods to validate the models limit their credibility and use. To foster good science for M&S in the medical device community, CDRH needs to leverage the expertise in industry and academia to advance M&S for regulatory uses.

##### **II. Topics for Discussion at the Public Workshop**

A large number of issues will be discussed at the conference with the overall theme being the application of modeling and simulation for medical devices at different stages in the total product life cycle. Topics include, but are not limited to the following:

- Model foundations for device design ideation;
- concept development and design optimization;
- modeling for robust design;
- design verification and validation;
- patient specific design;
- integration of modeling with clinical studies;
- modeling and device commercialization.

This public workshop may also form the basis for future discussions related to computer modeling and simulation that could benefit U.S. public health.

Dated: March 27, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **National Institutes of Health**

##### **National Institute Of Mental Health; 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 Mental Health Special Emphasis Panel; Mentoring Programs for HIV/AIDS Researchers 2.

**Date:** March 30, 2015.

**Time:** 11:00 a.m. to 1:00 p.m.

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

**Place:** National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

**Contact Person:** Aileen Schulte, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6140, MSC 9608, Bethesda, MD 20892-9608, 301-443-1225, [aschulte@mail.nih.gov](mailto:aschulte@mail.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.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: March 27, 2015.

**Carolyn A. Baum,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Food and Drug Administration**

**[Docket No. FDA-2011-N-0481]**

##### **Agency Information Collection Activities; Proposed Collection; Comment Request; New Animal Drugs for Investigational Uses**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on