

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.

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 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.

[FR Doc. 2015-07551 Filed 4-1-15; 8:45 am]

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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

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.

[FR Doc. 2015-07507 Filed 4-1-15; 8:45 am]

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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

the reporting and recordkeeping requirements for “New Animal Drugs for Investigational Uses”.

DATES: Submit either electronic or written comments on the collection of information by June 1, 2015.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB

for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

New Animal Drugs for Investigational Uses—21 CFR Part 511 (OMB Control Number 0910-0117)—(Extension)

FDA has the authority under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to approve new animal drugs. Section 512(j) of the Act (21 U.S.C. 360b(j)), authorizes FDA to issue regulations relating to the investigational use of new animal drugs. The regulations setting forth the conditions for investigational use of new animal drugs have been codified at 21 CFR part 511. If the new animal drug is only for tests in vitro or in laboratory research animals, the person distributing the new animal drug must maintain records showing the name and post office address of the expert or expert organization to whom it is

shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment or delivery. Before shipping a new animal drug for clinical investigations in animals, a sponsor must submit to FDA a Notice of Claimed Investigational Exemption (NCIE). The NCIE must contain, among other things, the following specific information: (1) Identity of the new animal drug, (2) labeling, (3) statement of compliance of any non-clinical laboratory studies with good laboratory practices, (4) name and address of each clinical investigator, (5) the approximate number of animals to be treated or amount of new animal drug(s) to be shipped, and (6) information regarding the use of edible tissues from investigational animals. Part 511 also requires that records be established and maintained to document the distribution and use of the investigational new animal drug to assure that its use is safe and that the distribution is controlled to prevent potential abuse. The Agency uses these required records under its Bio-Research Monitoring Program to monitor the validity of the studies submitted to FDA to support new animal drug approval and to assure that proper use of the drug is maintained by the investigator.

Investigational new animal drugs are used primarily by drug industry firms, academic institutions, and the government. Investigators may include individuals from these entities, as well as research firms and members of the medical professions. Respondents to this collection of information are the persons who use new animal drugs for investigational purposes.

FDA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
511.1(b)(4)	263	5.30	1,395	1	1,395
511.1(b)(5)	263	.26	69	8	552
511.1(b)(6)	263	.01	2	1	2
511.1(b)(8)(ii)	263	.06	15	2	30
511.1(b)(9)	263	.06	15	8	120
Total					2,099

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
511.1(a)(3)	263	2.07	545	1	545
511.1(b)(3)	263	5.30	1,395	1	1,395
511.1(b)(7)(ii)	263	5.30	1,395	3.5	4,882.5

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹—Continued

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
511.1(b)(8)(i)	263	5.30	1,395	3.5	4,882.5
Total					11,705

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of the time required for reporting requirements, record preparation, and maintenance for this collection of information is based on informal Agency communication with industry. Based on the number of sponsors subject to animal drug user fees, FDA estimates that there are 263 respondents. We use this estimate consistently throughout the table and calculate the “annual frequency per respondent” by dividing the total annual responses by number of respondents. Additional information needed to make a final calculation of the total burden hours (*i.e.*, the number of respondents, the number of recordkeepers, the number of NCIEs received, etc.) is derived from Agency records.

Dated: March 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-07539 Filed 4-1-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Evaluation of a Stepped Care Approach for Perinatal Depression Treatment in Obstetrics and Gynecology Clinics, DP15-005, initial review.

SUMMARY: This document corrects a notice that was published in the **Federal Register** on March 12, 2015 Volume 80, Number 48, page 13012. The time and date should read as follows:

Time and Date: 11:00 a.m.–6:00 p.m., April 1, 2015 (Closed).

FOR FURTHER INFORMATION CONTACT:

M. Chris Langub, Ph.D., Scientific Review Officer, CDC, 4770 Buford Highway NE., Mailstop F46, Atlanta, Georgia 30341, Telephone: (770) 488-3585, *EEO6@cdc.gov*.

The Director, Management Analysis and Services Office, has been delegated

the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2015-07545 Filed 4-1-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Using Longitudinal Data to Characterize the Natural History of Fragile X Syndrome to Improve Services and Outcomes, DD15-003, initial review.

SUMMARY: This document corrects a notice that was published in the **Federal Register** on March 25, 2015 Volume 80, Number 57, page 15798. The time and date should read as follows:

Time and Date: 11:00 a.m.–6:00 p.m., April 15, 2015 (Closed).

FOR FURTHER INFORMATION CONTACT:

M. Chris Langub, Ph.D., Scientific Review Officer, CDC, 4770 Buford Highway NE., Mailstop F46, Atlanta, Georgia 30341, Telephone: (770) 488-3585, *EEO6@cdc.gov*.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and

Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2015-07544 Filed 4-1-15; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than June 1, 2015.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10C-03, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting