

Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Frank Perrella, Center for Drug Evaluation and Research (HFD-320), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-3265.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled "PET Drugs—Current Good Manufacturing Practice (CGMP); Small Entity Compliance Guide." This guidance is intended to help small businesses better understand and comply with the regulations issued by FDA concerning CGMP for PET drugs. The guidance addresses resources, procedures, and documentation for all PET drug production facilities. In some cases, the guidance provides practical examples of methods or procedures that PET drug production facilities can use to comply with the CGMP requirements. FDA has prepared this guidance in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on compliance with CGMP for PET drugs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see

ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 211 have been approved under OMB control number 0910-0139, and the collections of information in 21 CFR part 212 have been approved under OMB control number 0910-0667.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: August 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-19867 Filed 8-4-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Billing Code 4140-01-P]

National Institutes of Health; Proposed Collection; Comment Request; Simulations for Drug Related Science Education

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute on Drug Abuse (NIDA), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously

published in the **Federal Register** on June 26, 2008 (Vol. 73, No. 124, page 36337) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after November 15, 2008, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Simulations for Drug Related Science Education. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* This is a request for a one-time clearance to evaluate an interactive multimedia module developed by *ArchieMD*. This evaluation seeks to determine whether the multimedia module *Archie MD: The Science of Drugs* (1) Increases students' knowledge in brain and heart biology and the effects drugs have on the body (2) Increases positive attitudes towards science education for high school students (3) Reinforce or instill negative attitudes towards substance abuse. In order to test the effectiveness of the interactive multimedia module, data will be collected in the form of pre and post test surveys from 10th and 11th grade high school students utilizing the developed module. The findings will provide valuable information regarding information pertaining to the use of interactive multimedia educational modules in high school science classrooms and their ability to increase knowledge and change attitudes and perceptions.

Frequency of Response: 3. *Affected Public:* High school students engaged with the *ArchieMD: The Science of Drugs* program. *Type of Respondent:* Participants will include high school students enrolled in the tenth and eleventh grade. *Estimated Total Annual Number of Respondents:* 360. *Estimated Number of Responses per Respondent:* 4. *Average Burden Hours per Response:* 25 minutes. *Estimated Total Annual Burden Hours Requested:* 450.00. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report. The estimated annualized burden is summarized below.

Type of respondents	Number of respondents	Frequency of response	Average burden hours per response	Estimated total burden hours requested
Participants-High School Students	360	3	.417	450.00
Total	360	3	.417	450.00

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information; (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 or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202-395-6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Cathrine Sasek, Coordinator, Science Education Program, Office of Science Policy and Communications, National Institute on Drug Abuse, 6001 Executive Blvd, Room 5237, Bethesda, MD 20892, or call non-toll-free number (301) 443-6071; fax (301) 443-6277; or by e-mail to *csasek@nida.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: August 1, 2011.

Mary Affeldt,

Executive Officer, (OM Director, NIDA).

[FR Doc. 2011-19877 Filed 8-4-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Chronic Illness and Anxiety.

Date: August 23, 2011.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Monica Basco, PhD, Scientific Review Officer, RPHB IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3220, MSC 7808, Bethesda, MD 20892, 301-496-7010, *bascoma@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Biology and Diseases of the Posterior Eye.

Date: September 13, 2011.

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

Agenda: To review and evaluate grant applications.

Place: Renaissance, Washington, DC Hotel, 999 Ninth Street, NW., Washington, DC 20001-4427.

Contact Person: Noni Byrnes, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5130, MSC 7840, Bethesda, MD 20892, (301)-435-1023, *byrnesn@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR-09-084: Developmental Biology Research.

Date: September 13-14, 2011.

Time: 1 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting).

Contact Person: John Burch, PhD, Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 3213, MSC 7808, Bethesda, MD 20892, 301-408-9519, *burchjb@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; MIT Laser Biomedical Research Center.

Date: September 14-16, 2011.

Time: 6 p.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Wardman Park Washington DC Hotel, 2660 Woodley Road, NW., Washington, DC 20008.

Contact: Xiang-Ning Li, MD, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5112, MSC 7854, Bethesda, MD 20892, 301-435-1744, *lixiang@csr.nih.gov*.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review

Group; Neural Basis of Psychopathology, Addictions and Sleep Disorders Study Section.

Date: September 15-16, 2011.

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

Agenda: To review and evaluate grant applications.

Place: Pier 5 Hotel, 711 Eastern Avenue, Baltimore, MD 21202.

Contact: Boris P Sokolov, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217A, MSC 7846, Bethesda, MD 20892, 301-408-9115, *bsokolov@csr.nih.gov*.

Name of Committee: Oncology 1-Basic Translational Integrated Review Group; Cancer Etiology Study Section.

Date: September 16, 2011.

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

Agenda: To review and evaluate grant applications.

Place: InterContinental Chicago Hotel, 505 North Michigan Avenue, Chicago, IL 60611.

Contact: Elaine Sierra-Rivera, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7804, Bethesda, MD 20892, 301-435-1779, *riverase@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 1, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-19878 Filed 8-4-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 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 Special