

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Philip L. Chao, Office of Policy and Planning (HF-23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0587.

#### **SUPPLEMENTARY INFORMATION:**

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

In the **Federal Register** of February 27, 2007, (72 FR 8756), FDA announced the availability of a draft guidance for industry entitled "Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administration." The term "complementary and alternative medicine" (CAM) encompasses a wide array of health care practices, products, and therapies that are distinct from practices, products, and therapies used in "conventional" or "allopathic" medicine.

In recent years, the practice of complementary and alternative medicine CAM has increased in the United States, and we have seen increased confusion as to whether certain products used in CAM are subject to regulation under the Federal Food, Drug, and Cosmetic Act (the act) or Public Health Service Act (PHS Act). We have also seen an increase in the number of CAM products imported into the United States. Therefore, the draft guidance discusses when a CAM product is subject to the act or the PHS Act.

The notice announcing the availability of the draft guidance provided a 60-day comment period, so the comment period for the draft guidance was scheduled to end on April 30, 2007. Unfortunately, due to a typographical error in the draft guidance itself (which stated that the comment period would be 90 days from the date

of the notice's publication in the **Federal Register**), we became aware that some members of the public believed that the comment period would or should end on May 28 or May 29, 2007. This confusion was compounded by another error that appeared at one section of FDA's Web site; the error, which appeared at the "Dockets Open for Comment" portion of the Web site where electronic comments are submitted, stated that the comment period would end on May 29, 2007. (In contrast, other sections of FDA's Web site retained the April 30, 2007, date.)

Given the amount of confusion as to the comment period, we are announcing that we will consider all comments on this draft guidance that are submitted through May 29, 2007. Previously submitted comments do not need to be resubmitted.

Additionally, we are aware of considerable confusion about the content of the draft guidance, which has been widely misinterpreted. Therefore, we want consumers and CAM practitioners to understand that the draft guidance does *not* contain or propose any new regulatory requirements for any complementary and alternative medicine CAM product marketed in the United States and does *not* affect any state licensing requirements for any CAM practitioner or any consumer's ability to buy or receive a CAM product or be treated by any CAM practitioner.

Public concern based on misinterpretations of the draft guidance has generated a large volume of comments to the docket. The large volume of comments has impeded our ability to identify and respond to extension requests. Consequently, we are addressing those unanswered extension requests by considering comments submitted through May 29, 2007.

##### **II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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. Electronic Access**

Persons with access to the Internet may obtain the draft guidance at <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: May 22, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 07-2610 Filed 5-22-07; 3:21 pm]

**BILLING CODE 4160-01-S**

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

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

##### **Proposed Collection; Comment Request; Application for the Pharmacology Research Associate Program**

*Summary:* In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of General Medical Sciences (NIGMS), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

*Proposed Collection: Title:* Application for the Pharmacology Research Associate Program. *Type of Information Collection Request:* Extension of a currently approved collection, OMB No. 0925-0378, expiration date August 31, 2007. *Form Numbers:* NIH 2721-1, NIH 2721-2. *Need and Use of Information Collection:* The Pharmacology Research Associate (PRAT) Program will use the applicant and referee information to award opportunities for training and experience in laboratory or clinical investigation to individuals with a Ph.D. degree in pharmacology or a related science, M.D., or other professional degree through appointments as PRAT Fellows at the National Institutes of Health or the Food and Drug Administration. The goal of the program is to develop leaders in pharmacological research for key positions in academic, industrial, and Federal research laboratories. *Frequency of Response:* Once a year. *Affected Public:* Individuals or households; Businesses or other for-profit. *Type of Respondents:* Applicants and Referees.

*The annual reporting burden is as follows:*

Type and number of respondents	Estimated number of responses per respondent	Estimated total responses	Average burden hours per responses	Estimated total annual burden hours requested
Applicants, 25 .....	1	25	8.00	200
Referees, 75 .....	1	75	1.75	131.25

*Total Number of Respondents:* 100.

*Total Number of Responses:* 100.

*Total Hours:* 331.25.

*The annualized cost to respondents is estimated at:*

*Applicants:* \$10,250.00.

*Referees:* \$6,562.50.

There are no Capital Costs, Operating costs, and/or Maintenance Costs to report.

**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) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**For Further Information Contact:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Sally Lee, NIGMS, NIH, Natcher Building, Room 2AN-18H, 45 Center Drive, MSC 6200, Bethesda, MD 20892-6200, or call non-toll-free number 301-594-2755 or e-mail your request, including your address to: < LeeS@nigms.nih.gov >.

**Comments Due Date:** Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: May 16, 2007.

**Sally Lee,**

*Acting Executive Officer, National Institute of General Medical Sciences, National Institutes of Health.*

[FR Doc. E7-10093 Filed 5-24-07; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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:** National Heart, Lung, and Blood Institute Special Emphasis Panel, Short Term Research Training (T35).

**Date:** July 19, 2007.

**Time:** 1 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:** Chang Sook Kim, PhD, Scientific Review Administrator, Review Branch, DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7190, Bethesda, MD 20892-7924, 301-435-0287, carolko@mail.nih.gov.

**Name of Committee:** National Heart, Lung, and Blood Institute Special Emphasis Panel, Cardiovascular Research Program Project.

**Date:** July 25, 2007.

**Time:** 1 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:** Keary A. Cope, PhD, Scientific Review Administrator, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7190, Bethesda, MD 20892-7924, 301-435-2222, copeka@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases

and Resources Research, National Institutes of Health, HHS).

Dated: May 17, 2007.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 07-2588 Filed 5-24-07; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Nursing Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 Nursing Research Initial Review Group.

**Date:** June 14-15, 2007.

**Time:** 8:15 am. to 6 p.m.

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

**Place:** Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

**Contact Person:** Jeffrey M. Chernak, PhD, Scientific Review Administrator, Office of Review, National Institute of Nursing Research, 6701 Democracy Plaza, Suite 710, MSC 4870, Bethesda, MD 20892, (301) 402-6959, chernakj@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: May 17, 2007.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 07-2589 Filed 5-24-07; 8:45 am]

**BILLING CODE 4140-01-M**