

the report it provided in a data file entitled "Center for Biologics Evaluation and Research Report of Scientific and Medical Literature and Information on Non-Standardized Allergenic Extracts in the Diagnosis and Treatment of Allergic Disease." The Agency is taking this action in response to input it received from the Allergenic Products Advisory Committee (APAC) at a meeting held on October 25, 2011, to allow interested persons additional time to submit comments.

**DATES:** Submit either electronic or written comments on the report by April 25, 2012.

**ADDRESSES:** Submit written requests for single copies of the report to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The data file may also be obtained by mail by calling CBER at 1-(800) 835-4709 or (301) 827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the data file document.

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

**FOR FURTHER INFORMATION CONTACT:** Paul E. Levine, Jr., Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, (301) 827-6210.

#### **SUPPLEMENTARY INFORMATION:**

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

In the **Federal Register** of September 26, 2011 (76 FR 59407), FDA published a notice with a 60-day comment period to request comments on its report of scientific and medical literature and information concerning the use of non-standardized allergenic extracts in the diagnosis and treatment of allergic disease. Comments on the report will allow FDA to fully evaluate the information contained in the report.

The Agency received comments in the APAC meeting held on October 25, 2011, that FDA should consider extending the comment period for the notice for several months. Members of the APAC expressed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to

the notice on FDA's report of scientific and medical literature and information concerning the use of non-standardized allergenic extracts in the diagnosis and treatment of allergic disease. Materials related to the report were discussed at this meeting and are available at: <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/AllergenicProductsAdvisoryCommittee/ucm247212.htm>. When it is completed, a transcript of the meeting will also be available at this Web page.

FDA has considered the comments from the APAC meeting and is extending the comment period for the notice until April 25, 2012. The Agency believes that an extension until April 25, 2012, allows adequate time for interested persons to submit comments without significantly delaying the evaluation of these important issues.

FDA welcomes comments regarding its report of scientific and medical literature and information concerning the use of non-standardized allergenic extracts in the diagnosis and treatment of allergic disease. In particular, FDA is interested in additional data regarding the use of these extracts that had been previously published in the medical or scientific literature. Unpublished data should include the following information, if available: Date(s) of collection; extract(s) studied and method of preparation; dose and route of administration; patient demography; and additional clinical information (including confirmatory testing, such as challenges or serum specific IgE determinations).

##### **II. Request for 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.

Dated: November 9, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-29483 Filed 11-15-11; 8:45 am]

**BILLING CODE 4160-01-P**

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

### **National Institutes of Health**

#### **National Institute of Environmental Health Sciences; Notice of Meeting**

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Interagency Breast Cancer and Environmental Research Coordinating Committee.

The meeting will be open to the public, 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.

*Name of the Committee:* Interagency Breast Cancer and Environmental Research Coordinating Committee (IBCCRC).

*Date:* December 14, 2011.

*Time:* 11 a.m. to 2 p.m.

*Agenda:* The purpose of the meeting is to review the consensus study (<http://www.iom.edu/Activities/Environment/BreastCancerEnvironment.aspx>) focused on breast cancer and the environment that is scheduled to be released by Institute of Medicine (IOM) December 7, 2011. In advance of the meeting, the detailed meeting agenda will be available on the web at <http://www.niehs.nih.gov/about/orgstructure/boards/ibccrc/>.

*Place:* NIEHS/National Institutes of Health, Building 4401, East Campus, 79 T.W. Alexander Drive, Research Triangle Park, NC 27709. (This meeting will be conducted remotely. To attend the meeting, please RSVP via email to [ibccrc@niehs.nih.gov](mailto:ibccrc@niehs.nih.gov) at least 10 days in advance and instructions for joining the meeting will be provided.)

*Contact Person:* Gwen Collman, Ph.D., Director, Division of Extramural Research and Training, Nat. Inst. of Environmental Health Sciences, National Institutes of Health, 615 Davis Dr., KEY615/3112, Research Triangle Park, NC 27709, (919) 541-4980, [collman@niehs.nih.gov](mailto:collman@niehs.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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: November 8, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011-29610 Filed 11-15-11; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Alcohol Abuse and Alcoholism; 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 on Alcohol Abuse and Alcoholism Special Emphasis Panel; NIAAA Member Conflict Applications.

*Date:* November 30, 2011.

*Time:* 1 p.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* NIAAA, NIH, 5635 Fishers Lane, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Ranga Srinivas, Ph.D., Chief, Extramural Project Review Branch EPRB, NIAAA, National Institutes of Health, 5365 Fishers Lane, Room 2085, Rockville, MD 20852, (301) 451-2067, [srinivar@mail.nih.gov](mailto:srinivar@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)

Dated: November 8, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011-29609 Filed 11-15-11; 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 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:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Reproduction Metabolism.

*Date:* December 8-9, 2011.

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

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Reed A Graves, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6166, MSC 7892, Bethesda, MD 20892, (301) 402-6297, [gravesr@csr.nih.gov](mailto:gravesr@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: November 9, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011-29608 Filed 11-15-11; 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: Behavioral and Social Approaches to Preventing HIV/AIDS.

*Date:* November 29, 2011.

*Time:* 12 p.m. to 2 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Mark P. Rubert, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, (301) 435-1775, [rubertm@csr.nih.gov](mailto:rubertm@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Drug Addiction and Ion Channel Function.

*Date:* December 5, 2011.

*Time:* 12:30 p.m. to 2:30 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:* Deborah L. Lewis, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4183, MSC 7850, Bethesda, MD 20892, (301) 408-9129, [lewisdeb@csr.nih.gov](mailto:lewisdeb@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Neural Cell Injury and Death.

*Date:* December 7, 2011.

*Time:* 1 p.m. to 3 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:* Toby Behar, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4136, MSC 7850, Bethesda, MD 20892, (301) 435-4433, [behart@csr.nih.gov](mailto:behart@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Vascular and Hematology.

*Date:* December 7, 2011.

*Time:* 2 p.m. to 5 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:* Larry Pinkus, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4132, MSC 7802, Bethesda, MD 20892, (301) 435-1214, [pinkusl@csr.nih.gov](mailto:pinkusl@csr.nih.gov).