

in the **Federal Register** of Thursday, October 20, 2011, the following correction is made:

1. On page 65199, in the first column, in the **DATES** section, the date "January 18, 2011" is corrected to read "January 18, 2012."

Dated: November 9, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-29485 Filed 11-15-11; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0002]

#### Neurological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Neurological Devices Panel of the Medical Devices Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on February 10, 2012, from 8 a.m. to 6 p.m.

*Location:* Hilton Washington, DC North/Gaithersburg, salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel telephone number is (301) 977-8900.

*Contact Person:* Avena Russell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1535, Silver Spring, MD 20993-0002, [Avena.Russell@fda.hhs.gov](mailto:Avena.Russell@fda.hhs.gov), (301) 796-3805, or FDA Advisory Committee Information Line, 1-(800) 741-8138, (301) 443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the

appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* On February 10, 2012, the committee will discuss and make recommendations regarding the possible reclassification of cranial electrotherapy stimulator (CES) devices. On August 8, 2011 (76 FR 48062), FDA issued a proposed rule which, if made final, would make CES devices Class III requiring premarket approval. In response to the proposed rule, FDA received petitions under section 515(b)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(b)(2)(B)) requesting a change in classification. The reclassification petitions are available for public review and comment at <http://www.regulations.gov> under docket number FDA-2011-N-0504. The committee discussion will include the existing data to support CES safety and effectiveness and whether the data are sufficient to develop special controls to support regulation of these devices under Class II.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 6, 2012. Oral presentations from the public will be scheduled between approximately 10 a.m. and 11 a.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 27, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the

speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 30, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact James Clark at [James.Clark@fda.hhs.gov](mailto:James.Clark@fda.hhs.gov) or (301) 796-5293, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 9, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-29528 Filed 11-15-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0599]

#### 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; Extension of Comment Period

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

**ACTION:** Notice; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending to April 25, 2012, the comment period for the notice 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 that appeared in the **Federal Register** of September 26, 2011 (76 FR 59407). In the notice, FDA requested comments from public and private stakeholders on

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 (IBCERC).

**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/ibcercc/>.

**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 [ibcercc@niehs.nih.gov](mailto:ibcercc@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)