

guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 29, 2011.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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 request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to 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:** Elizabeth Giaquinto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6155, Silver Spring, MD 20993-0002, 301-796-3416.

#### **SUPPLEMENTARY INFORMATION:**

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

FDA is announcing the availability of a draft guidance entitled "Media Fills for Validation of Aseptic Preparations for Positron Emission Tomography (PET) Drugs." Most PET drugs are designed for parenteral administration and are produced by aseptic processing. The goal of aseptic processing is to make a product that is free of microorganisms and toxic microbial byproducts, most notably bacterial endotoxins. The media fill is the performance of an aseptic manufacturing procedure using a sterile microbiological growth medium in place of the drug solution to test whether the aseptic procedures are adequate to prevent contamination during actual drug production. This draft guidance takes the form of questions and answers written specifically to help manufacturers comply with the Agency's current good manufacturing practices for PET drugs (part 212 (21 CFR part 212)) regarding media fills.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on media fills and process simulations for PET drugs.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 draft 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 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/Guidance/ComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: September 26, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-25196 Filed 9-29-11; 8:45 am]

**BILLING CODE 4160-01-P**

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

##### **Food and Drug Administration**

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

##### **National Mammography Quality Assurance 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:** National Mammography Quality Assurance 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 November 4, 2011, from 8 a.m. to 6 p.m.

**Location:** Holiday Inn, Ballroom, 2 Montgomery Village Ave, Gaithersburg, MD 20879. The hotel's telephone number is 301-948-8900.

**Contact Person:** Shanika Craig, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-6639, [Shanika.Craig@fda.hhs.gov](mailto:Shanika.Craig@fda.hhs.gov), 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 November 4, 2011, the committee will provide advice and recommendations on the following issues: (1) Proposed changes to the Mammography Quality Standard Act (MQSA) policies and inspection procedures; (2) accreditation body review of soft copy mammography images; and (3) reporting breast density on mammography reports and patient lay summaries. The committee will also receive updates on the MQSA program and the status of the Full Field Digital Mammography universal quality control manual.

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 October 21, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. immediately following lunch. 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 October 13, 2011. 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 October 14, 2011.

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: September 26, 2011.

**Jill Hartzler Warner,**  
Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011-25148 Filed 9-29-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases; 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:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, FGF23 Physiology.

*Date:* November 7, 2011.

*Time:* 12 p.m. to 1 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Michele L. Barnard, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 753, 6707 Democracy Boulevard, Bethesda, MD 20892-2542, (301) 594-8898, [barnardm@extra.niddk.nih.gov](mailto:barnardm@extra.niddk.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Bariatric Surgery Ancillary Studies.

*Date:* November 9, 2011.

*Time:* 2 p.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Paul A. Rushing, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 747, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8895, [rushingp@extra.niddk.nih.gov](mailto:rushingp@extra.niddk.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Gene Networks in Macrophage-Adipocyte Interactions P01.

*Date:* November 30, 2011.

*Time:* 1 p.m. to 3:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Paul A. Rushing, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 747, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8895, [rushingp@extra.niddk.nih.gov](mailto:rushingp@extra.niddk.nih.gov).

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Intestinal Inflammation P01.

*Date:* December 7, 2011.

*Time:* 1 p.m. to 3:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Paul A. Rushing, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 747, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8895, [rushingp@extra.niddk.nih.gov](mailto:rushingp@extra.niddk.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: September 26, 2011.

**Jennifer S. Spaeth,**

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-25245 Filed 9-29-11; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-3338-EM; Docket ID FEMA-2011-0001]

### Vermont; Emergency and Related Determinations

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This is a notice of the Presidential declaration of an emergency for the State of Vermont (FEMA-3338-EM), dated August 29, 2011, and related determinations.

**DATES:** *Effective Date:* August 29, 2011.

**FOR FURTHER INFORMATION CONTACT:** Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that, in a letter dated August 29, 2011, the President issued an emergency declaration under the authority of the Robert T. Stafford