

of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committees:* Cardiovascular and Renal Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

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

*Date and Time:* The meeting will be held on May 2, 2011, from 8 a.m. to 4 p.m.

*Location:* FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center, rm. 1503, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You", click on "White Oak Conference Center Parking and Transportation Information for FDA Advisory Committee Meetings". Please note that visitors to the White Oak Campus must enter through Building 1.

*Contact Person:* Nicole Vesely, Pharm.D., Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, WO31-2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, e-mail: [nicole.vesely@fda.hhs.gov](mailto:nicole.vesely@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 May 2, 2011, the committees will discuss safety considerations of ultrasound contrast agents (materials intended to improve the clarity of ultrasound imaging), particularly related to new information and developments since the prior Advisory Committee meeting on the same topic on June 24, 2008. The discussion will include the results of required postmarketing safety studies and data from postmarketing surveillance. Specific drugs to be discussed include: (1) New drug

application (NDA) 21-064, perflutren lipid microsphere injectable suspension, Lantheus Medical Imaging, Inc.; (2) NDA 20-899, perflutren protein-type A microspheres injectable suspension, GE Healthcare; and (3) the investigational new drug (IND) application for sulfur hexafluoride microbubble injection, Bracco Diagnostics, Inc. Perflutren lipid microsphere injectable suspension and perflutren protein-type A microspheres injectable suspension are indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border (improve the clarity of imaging of specific areas of the left lower side of the heart).

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 committees. Written submissions may be made to the contact person on or before April 18, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.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 April 8, 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 April 11, 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 Nicole Vesely 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 March 22, 2011.

**Leslie Kux,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 2011-8284 Filed 4-6-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

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

#### Safety and Efficacy of Hypnotic Drugs; Public Meeting

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

**ACTION:** Notice of public meeting.

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The Food and Drug Administration (FDA) is announcing a public meeting to discuss the safety and efficacy of drugs for the treatment of insomnia. The Division of Neurology Products (DNP) in FDA's Center for Drug Evaluation and Research and the Pharmaceutical Education and Research Institute (PERI) are cosponsoring the 2-day meeting, with the first day centered on issues of efficacy and the second day on safety.

*Date and Time:* The public meeting will be held on Tuesday, May 10, and Wednesday, May 11, 2011, from 8 a.m. to 5 p.m.

*Location:* The public meeting will be held at the Bethesda Marriott, 5151 Pooks Hill Rd., Bethesda, MD 20814.

*Contact:* Margaret Bogie, 703-276-0178, ext. 115, Fax: 703-276-0069; or Cathleen Michaloski, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4342, Silver Spring, MD 20993, 301-796-1123, e-mail:

[Cathleen.michaloski@fda.hhs.gov](mailto:Cathleen.michaloski@fda.hhs.gov).

*Accommodations:* Attendees are responsible for their own accommodations. Reservations can be

made on a space available basis at the Bethesda Marriott Pooks Hill (see *Location*).

*Registration:* You are encouraged to register at your earliest convenience.

A registration fee will be charged to help defray the costs of rental of the meeting spaces, meals and snacks provided, and to cover travel costs incurred by invited speakers, and other costs. The cost of registration is as follows:

**One-Day Rates:**

Government: \$475  
Academic: \$795  
Industry: \$895

**Two-Day Rates:**

Government: \$875  
Academic: \$1,495  
Industry: \$1,695

Registration fees will be waived for invited speakers and members of the working group. If you need special accommodations due to a disability, please contact Margaret Bogie or Cathleen Michaloski (see *Contact*) at least 7 days in advance of the meeting.

*Registration Instructions:* For further details on how to register for the public meeting, contact Margaret Bogie or Cathleen Michaloski (see *Contact*).

**SUPPLEMENTARY INFORMATION:** Insomnia is a common disorder in the United States, yet it remains relatively poorly understood. Questions remain, for example, about the definition of insomnia and the classification of patients with the disorder. A better understanding of insomnia should help lead to safer and more effective treatment. A number of medications have been approved for insomnia, and many experimental medications are currently in development. New concerns have arisen about the most appropriate way to evaluate both the safety and the efficacy of medications for insomnia, particularly given that they may differ in important characteristics, including both pharmacodynamic and pharmacokinetic properties.

DNP and PERI plan for the first day of the meeting to center on issues of efficacy, including the evolving definition of insomnia, the classification of patients with this disorder, and the measurement of clinically relevant outcomes, including the choice of endpoints, subjective versus objective assessments, and duration of effect. The second day of the meeting will center on safety issues of hypnotic drugs, including the nature and prevalence of adverse events (AEs) related to the use of hypnotic drugs and evaluation of these AEs with a concentration on psychovigilance testing and driving-related tests.

Additional information on the conference, program, and registration procedures is available on the Internet at [http://peri.org/course\\_details.cfm?course=2072](http://peri.org/course_details.cfm?course=2072). FDA has verified the PERI Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.

Dated: April 4, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-8285 Filed 4-6-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0013]

#### Statement of Organizations, Functions, and Delegations of Authority

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has reorganized the Center for Drug Evaluation and Research (CDER), Office of Surveillance and Epidemiology (OSE). This reorganization includes the organizations and their substructure components as listed in this document. This reorganization includes the establishment of six Staffs: Executive Operations and Strategic Planning Staff, Regulatory Science Staff, Regulatory Affairs Staff, Program Management and Analysis Staff, Project Management Staff, and Technical Information Staff. It will also include Office of Medication Error Prevention and Risk Management (OMEPRM) and Office of Pharmacovigilance and Epidemiology (OPE) under OSE. OMEPRM will consist of the Division of Risk Management and the Division of Medication Error Prevention and Analysis. OPE will consist of the Division of Epidemiology I and Division of Epidemiology II and the Division of Pharmacovigilance I and Division of Pharmacovigilance II. Also included are the abolishment of Business Process Improvement Staff, Regulatory Policy Staff, and Review Management Staff within OSE Immediate Office.

**FOR FURTHER INFORMATION CONTACT:**

Karen Koenick, Center for Drug Evaluation and Research (HFD-063), Food and Drug Administration, 11919 Rockville Pike, rm. 324, Rockville, MD 20852, 301-796-4422.

## I. Summary

The Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970; 60 FR 56605, November 9, 1995; 64 FR 36361, July 6, 1999; and 72 FR 50112, August 30, 2007) is amended to reflect the restructuring of CDER, FDA as follows.

## II. Organization

CDER is headed by the Director, and includes the following organizational unit:

### *Office of Surveillance and Epidemiology*

1. Provides leadership, direction, planning, budgeting, management, and supervision of Divisions and Staffs; and premarketing and postmarketing risk assessment program operations.

2. Develops and maintains international and national contact with regulators.

3. Develops, coordinates, and implements postmarket risk assessment policy, guidance, and interpretations.

4. Initiates regulation development and enhancement.

5. Coordinates and implements policies and initiatives, including information management initiatives across the Agency.

### *Regulatory Science Staff*

1. Provides leadership, direction, and coordination for OSE regulatory research activities.

2. Develops and manages relationships with outside scientific groups that interface with OSE scientists on a variety of projects that relate to OSE's drug safety mission. These outside groups include academic organizations, private organizations, and other Federal Agencies.

3. Coordinates the access to large databases for pharmacoepidemiologic and pharmacovigilance studies, as well as to the outside scientists with drug safety expertise to collaborate with CDER.

4. Develops regulatory research programs that will support OSE as a whole, including risk management, pharmacovigilance, and medication error detection and prevention; in addition to epidemiology.

### *Regulatory Affairs Staff*

1. Responsible for the coordination and implementation of regulatory policies by staff within OSE by coordinating the development and upkeep of guidances, MAPPs, and standard operating procedures, answering regulatory questions, managing the process for waivers of