4160-01-P

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.

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, email: 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. 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.