

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Drug Safety and Risk Management 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: Drug Safety and Risk Management 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 May 18 and 19, 2005, from 8:30 a.m. to 5 p.m.

Location: Holiday Inn, The Ballrooms, 8777 Georgia Ave., Silver Spring, MD.

Contact Person: Shalini Jain, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, e-mail: jains@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512535. Please call the Information Line for up-to-date information on this meeting.

Agenda: This is the first in a series of meetings related to the issues in drug safety and FDA. This 2-day meeting will explore issues related to FDA's

risk assessment program for marketed drugs. There are a number of methods that FDA uses in risk assessment of marketed drugs, including review and analysis of spontaneous reports of adverse events, drug use data, healthcare administrative data, epidemiologic and observational studies, clinical trials, and active surveillance systems. Considerations will include the advantages and disadvantages of the current system for safety signal detection, and proposals for short-term and long-term ways to improve the current system. The background materials for this meeting will be posted 1 business day before the meeting on the FDA Web site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. (Click on the year 2005 and scroll down to the Drug Safety and Risk Management Advisory Committee.)

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 by May 9, 2005. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon on May 18, 2005, and between approximately 11:10 a.m. and 11:40 a.m. on May 19, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 9, 2005, 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.

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

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disabilities or special needs. If you require special accommodations due to a disability, please contact Shalini Jain at least 7 days in advance of the meeting.

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

Dated: April 7, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

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