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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Dermatologic and Ophthalmic Drugs 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 Committees: Drug Safety and Risk Management Advisory Committee and the Dermatologic and Ophthalmic Drugs 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 26 and 27, 2004, from 8 a.m. to 5 p.m.

Location: Hilton, The Ballrooms, 620 Perry Pkwy., Gaithersburg, 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), codes 3014512535 or 3014512534. Please call the Information Line for up-to-date information on this meeting.

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The background materials for this meeting will become available no later than 1 business day before the meeting and will be posted at: *www.fda.gov/ohrms/dockets/ac/acmenu.htm.* (Click on the year 2003 and scroll down to either the Drug Safety and Risk Management Advisory Committee or the Dermatologic and Ophthalmic Drugs Advisory Committee meetings.)

Agenda: The committee will discuss the following topics: (1) The effectiveness of the isotretinoin risk management program for the prevention of fetal exposure to ACCUTANE and its generic equivalents, and (2) consider whether changes to this isotretinoin risk management program would be appropriate.

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 February 16, 2004. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon on February 26, 2004, and between approximately 8:30 a.m. and 9:30 a.m. on February 27, 2004. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 16, 2004, 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

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: 12/15/03
December 15, 2003.

William K. Hubbard,
Associate Commissioner for Policy and Planning.

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

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