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Certifier A. Corbin

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 5, 2004, from 8 a.m. to 5 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville MD.

Contact Person: Shalini Jain, Center for Drug Evaluation and Research (HFD–21), 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. Background materials for this meeting when available will be posted on the Internet 1 business day before the meeting at *www.fda.gov/ohrms/dockets/ac/acmenu.htm*.

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Agenda: From 8 a.m. to 3 p.m., the committee will discuss medication errors relating to the labeling and packaging of various drug products in low-density polyethylene plastic vials. From 3 p.m. to 5 p.m., the committee will receive a progress report on the new drug application (NDA) 21–107, LOTRONEX (alosetron hydrochloride), GlaxoSmithKline, Risk Management Program.

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 April 27, 2004. Oral presentations from the public will be scheduled between approximately 11 a.m. and 11:30 a.m. and between approximately 3 p.m. and 3:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 27, 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: 4/5/04
April 5, 2004.

Peter J. Pitts,
Associate Commissioner for External Relations.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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