
Dated: June 20, 2011.

Leslie Kux,
Acting Assistant Commissioner for Policy.

FOR FURTHER INFORMATION CONTACT:

Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[DOCKET NO. FDA–2011–N–0002]

Joint Meeting of the Gastrointestinal Drugs Advisory Committee and the 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). At least one portion of the meeting will be closed to the public.

Name of Committees: Gastrointestinal 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 July 20, 2011, from 8 a.m. to 9 a.m., unless public participation does not last that long; from 9 a.m. to 1 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information.

FDA generally makes background material available to the public no later than 2 business days before the meeting or follows other procedures to make such material available to the public. There is no background material that is publicly available for this meeting.

Procedure: On July 20, 2011, from 8 a.m. to 9 a.m., the meeting is open to the public. 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 on or before July 6, 2011. Oral presentations from the public will be scheduled between approximately 8 a.m. to 9 a.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 June 27, 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 June 28, 2011.

Closed Committee Deliberations: On July 20, 2011, from 9 a.m. to 1 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)). During this session, the committees will discuss the drug development program of an investigational gastroenterology drug.

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 Kristine T. Khuc 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.

Dated: June 21, 2011.

Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.

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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) is announcing that it has reorganized the Center for Drug Evaluation and Research (CDER), Office of Compliance. This reorganization includes the organizations and substructure components as listed in this document. This document is announcing availability of the Staff Manual Guide that explains the details of this reorganization.

FOR FURTHER INFORMATION CONTACT: Karen Koenick, Center for Drug Evaluation and Research (HFD–063), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301–796–4422.

I. Summary

The Statement of Organization, Functions, and Delegations of Authority for CDER (35 FR 3685, February 25, 1970, 60 FR 56605, November 9, 1995, 64 FR 36361, June 7, 1999, 72 FR 50112,