

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

Joint Meeting of the Nonprescription Drugs Advisory Committee and the
Gastrointestinal Drugs Advisory Committee

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: Nonprescription Drugs Advisory Committee and the Gastrointestinal 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 June 21, 2002, from 8 a.m. to 4:30 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Sandra Titus, 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, or e-mail: Tituss@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area) code 12541. Please call the Information Line for up-to-date information on this meeting.

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Agenda: The committees will consider the safety and efficacy of new drug application (NDA) 21–229, proposing over-the-counter (OTC) use of PRILOSEC1 (omeprazole magnesium), AstraZeneca LP/Procter and Gamble, for the prevention of the symptoms of frequent heartburn. The sponsor proposes a 20 milligram dose to be taken for 14 days. The background material for this meeting will be posted one working day before the meeting under the Nonprescription Drugs Advisory Committee (NDAC) on the Dockets Management Branch Web site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. (Click on the year 2002 and scroll down to NDAC.)

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 June 12, 2002. Oral presentations from the public will be scheduled on June 21, 2002, between approximately 8:15 a.m. and 9:15 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 12, 2002, 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 Sandra Titus 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: 4-29-02
April 29, 2002.

Linda A. Suydam

Linda A. Suydam,
Senior Associate Commissioner for
Communications and Constituent Relations. *st*

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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Regina Adesoro

