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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

**Joint Meeting of the Nonprescription Drugs Advisory Committee and the
Gastrointestinal 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: Nonprescription Drugs Advisory Committee and the Gastrointestinal Drugs 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 October 20, 2000, 8 a.m. to 5 p.m.

Location: Holiday Inn, The Ballroom, Two Montgomery Ave., Gaithersburg, MD.

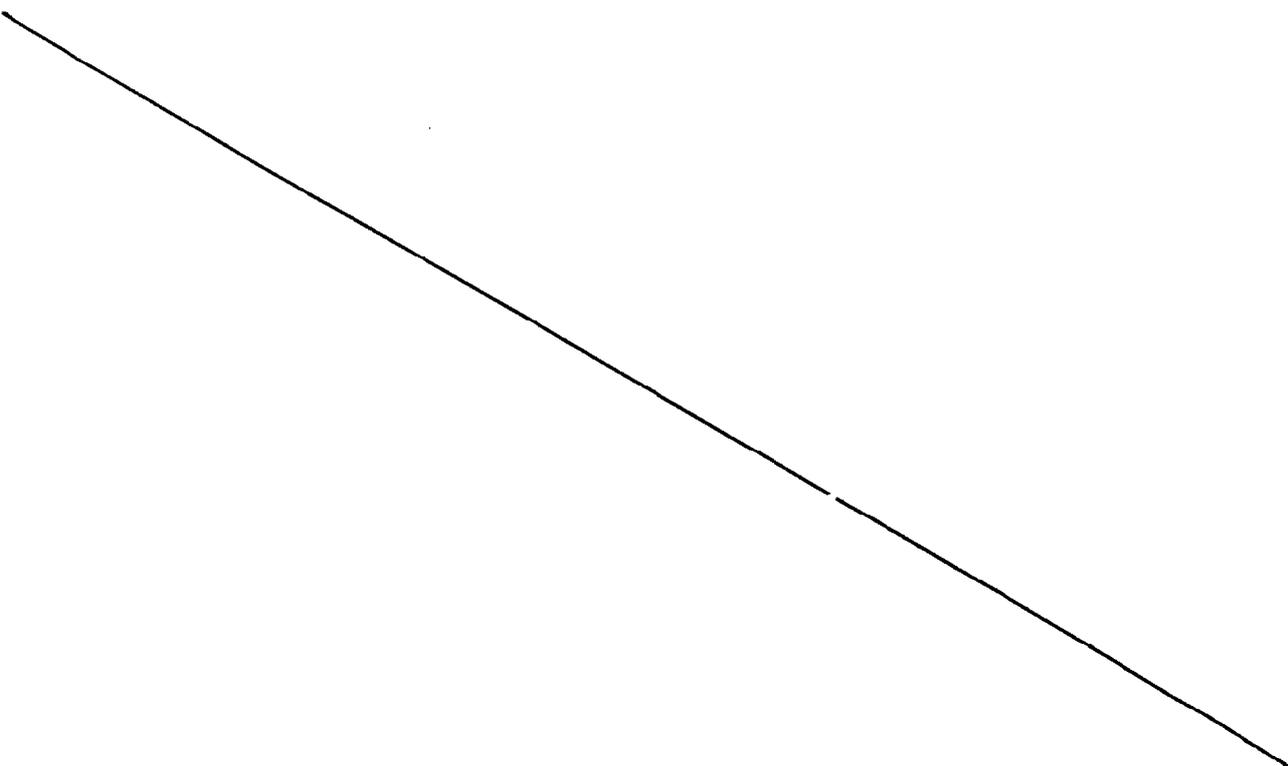
Contact Person: Sandra L. Titus or Thomas H. Perez, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301-827-7001, or e-mail: PerezT@cder.fda.gov, or FDA Advisory Committee Information 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.

Agenda: The committees will consider new drug application (NDA) 21-229 proposing over-the-counter (OTC) use of Prilosec® (omeprazole), Astra-Zeneca with distribution by Procter and Gamble. This is proposed to: (1) Relieve heartburn, acid indigestion and sour stomach, and (2)

prevent heartburn, acid indigestion, and sour stomach brought on by consuming food and beverages, or associated with events such as stress, hectic lifestyle, lying down, or exercise.

The background material that the committees will review will be available 1 business day before the meeting on the Internet at: <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. Click on the year 2000 and then locate the Nonprescription Drugs Advisory Committee meeting for October 20, 2000.

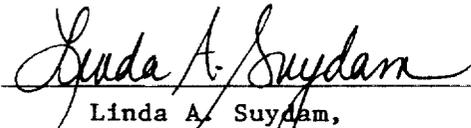
Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 9, 2000. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. on October 20, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 9, 2000, 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.



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

2).

Dated: 8/21/00
August 21, 2000



Linda A. Suydam,
Senior Associate Commissioner.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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Jen Windsor