

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Meeting of the Nonprescription Drugs Advisory Committee With Consultation From the Pulmonary and Allergy Drugs Advisory Committee and the Dermatologic and Ophthalmologic 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Nonprescription 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 April 22, 2002, from 8 a.m. to 5 p.m. and on April 23, 2002, from 9 a.m. to 12 noon.

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, 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.

Agenda: On April 22, 2002, the committee will consider the safety and efficacy of new drug applications (NDA): NDA 19-658, CLARITIN Tablet; NDA 20-704, CLARITIN RediTab; and NDA 20-641, CLARITIN Syrup. These three CLARITIN products (loratadine, Schering-Plough Corp.) are immediate release formulations of the products that are proposed for over-the-counter

(OTC) use for the relief of symptoms associated with allergic rhinitis and chronic idiopathic urticaria (CIU). The primary purpose of the meeting is to discuss CIU as an OTC indication. The background material for this meeting will be posted under the Nonprescription Drugs Advisory Committee (NDAC) Docket 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 April 12, 2002. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on April 22, 2002, and the meeting will be closed to the public between approximately 9 a.m. and 12 noon on April 23, 2002. Time allotted for each presentation may be limited. Priority for presentations will be given to those who demonstrate that they plan to address CIU as an OTC indication. Those desiring to make formal oral presentations should notify the contact person before April 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.

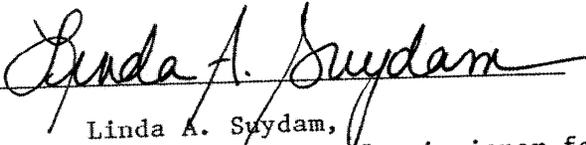
FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Sandra Titus at least 7 days in advance of the meeting.

Closed Committee Deliberations: On April 23, 2002, from approximately 9 a.m. to 12 noon, the meeting will be closed to provide an annual update and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

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

2).

Dated: 3-25-02
March 25, 2002.



Linda A. Sydam,
Senior Associate Commissioner for
Communications and Constituent Relations.

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