April 22, 2002 Draft Agenda

Nonprescription Drugs Advisory Committee

Holiday Inn, Bethesda MD

Issue: The committee will consider the safety and efficacy of new drug applications, (NDA) 19-658, Claritin Tablet, NDA 20-704, Claritin RediTab, and NDA 20-641, Claritin Syrup. These three Claritin® products (loratadine, Schering-Plough Corporation) 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.

8:00	Introduction and Conflict of Interest Statement
8:15	FDA Overview of Issues
8:30	Schering Plough Presentation
9:30	Questions to Schering Plough
10:00	Break
10:30	FDA Presentation
11:30	Questions to FDA
12:00	Lunch
1:00	Open Public Hearing
2:00	Discussion by Committee on the questions posed by the FDA
5:00	Probable Adjournment

Background: 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.)

Open Public Hearing: 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 on April 22, 2002, between approximately 1 p.m. and 2 p.m. 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.

Contact Person: Sandra Titus, Ph.D., 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.