

Dated: February 14, 1995.

Linda A. Suydam,

Interim Deputy Commissioner for Operations.

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Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1-800-741-8138 or 301-443-0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETINGS: The following advisory committee meetings are announced:

Allergenic Products Advisory Committee

Date, time, and place. March 10, 1995, 9 a.m., Woodmont Office Complex I, conference room 400-N, 1401 Rockville Pike, Rockville, MD.

Type of meeting and contact person. This meeting will be held by a telephone conference call. A speaker telephone will be provided in the conference room to allow public participation in the meeting. Open committee discussion on review of research, 9 a.m. to 10 a.m.; closed committee deliberations, 10 a.m. to 11:05 a.m.; open public hearing, 11:05 a.m. to 12:05 p.m., unless public participation does not last that long; Jack Gertzog or Sandy Salins, Center for Biologics Evaluation and Research (HFM-21), Food and Drug Administration, 1401 Rockville Pike,

Bethesda, MD 20852, 301-827-0314, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Allergenic Products Advisory Committee, code 12388.

General function of the committee.

The committee reviews and evaluates data on the safety and effectiveness of allergenic biological products intended for use in the diagnosis, prevention, or treatment of human disease.

Agenda—Open public hearing.

Interested persons requesting to present data, information, or views, orally or in writing, on issues pending before the committee, should communicate with the contact person.

Open committee discussion. The committee will discuss the intramural scientific program of the Laboratory of Immunobiochemistry and the clinical research programs of individuals in the Division of Allergenic Products and Parasitology.

Closed committee deliberations. The committee will discuss the intramural scientific program. This portion of the meeting will be closed to prevent disclosure of personal information concerning individuals associated with the research program, disclosure of which would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)).

Arthritis Advisory Committee

Date, time, and place. March 27, 1995, 8:30 a.m., Holiday Inn—Silver Spring, Plaza Ballroom, 8777 Georgia Ave., Silver Spring, MD. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing a joint meeting on March 28, 1995, with the Nonprescription Drugs Advisory Committee.

Type of meeting and contact person.

Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 12:30 p.m.; closed committee deliberations, 12:30 p.m. to 5:30 p.m.; Isaac F. Roubein, Center for Drug Evaluation and Research (HFD-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Arthritis Advisory Committee, code 12532.

General function of the committee.

The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in arthritic conditions.

Agenda—Open public hearing.

Interested persons may present data,

information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before March 16, 1995, 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 required to make their comments.

Open committee discussion. The committee will discuss the new drug application (NDA) 18-922, Lodine® (etodolac) Wyeth-Ayerst Laboratories, which is proposed for the treatment of rheumatoid arthritis.

Closed committee deliberations. The committee will review trade secret and/or confidential commercial information relevant to pending investigational new drugs. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes