DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also sets forth a summary of the procedures governing committee meetings and methods by which interested persons may participate in open public hearings conducted by the committees and is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770–776 (5 U.S.C. App. I)) and FDA regulations (21 CFR Part 14) relating to advisory committees. The following advisory committee meeting is announced:

Pulmonary-Allergy Drugs Advisory Committee

Date, time, and place. May 13, 8 a.m., Conference Rm. 10, Bldg. 31, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD.

Type of meeting and contact person. Open committee discussion, 8 a.m. to 11 a.m.; open public hearing, 11 a.m. to 12 m.; open committee discussion, 12 m. to 4 p.m.; Conrad J. Ledet, National Center for Drugs and Biologics (HFN–160), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3500. If any special arrangements or accommodations are needed, contact Mr. Ledet by May 6.

General function of the committee. The committee reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.

Open committee discussion. The committee with discuss whether metaproterenol metered dose inhalers should continue to be marketed over-the-counter (OTC). The committee will also discuss sulfiting agents used as antioxidants in drug products and the pharmacokinetics and labeling of sustained release theophylline preparations.

As part of the OTC Drug Review proceeding on Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products, the agency proposed that metaproterenol sulfate as a pressurized metered dose inhaler could be classified as safe and effective for OTC use (tentative final monograph for OTC Bronchodilator Drug Products at 47520, October 28, 1982). The Pulmonary-Allergy Drugs Advisory Committee's discussion and recommendations regarding such products will be considered in the agency's preparation of the final rule for OTC bronchodilator drugs.

FDA is not providing the usual 15-day advance notification of the May 13 meeting of the Pulmonary-Allergy Drugs Advisory Committee because it is the Commissioner of Food and Drugs judgment that it would be inappropriate to delay the committee's deliberation on the subject of the continued OTC marketing of metaproterenol metered dose inhalers. This judgment was made because FDA has received a number of public comments alleging that there is a potential hazard due to OTC marketing of metaproterenol metered dose inhalers. These comments claim that, because of the possibility that this drug may be abused, it continued availability without a prescription may encourage some asthmatics to delay seeking needed medical advice.

FDA public advisory committee meetings 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. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open 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 chairman determines will facilitate the committee's work.

Meetings of advisory committees shall be conducted, as far as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairman's discretion.

Persons interested in specific agenda items to be discussed in open session may ascertain from the contact person the approximate time of discussion.

A list of committee members and summary minutes of meetings may be requested from the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday. The FDA regulations relative to public advisory committees may be found in 21 CFR Part 14.

Dated: April 27, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83–11706 Filed 4–28–83; 10:49 am]

BILLING CODE 4160–01–M