Pulmonary-Allergy Drugs Advisory Committee

Date, time, and place. March 28 and 29, 1996, 8:30 a.m., Quality Hotel, Maryland Ballroom, 8727 Colesville Rd., Silver Spring, MD.

Type of meeting and contact person. Open public hearing, March 28, 1996, 8:30 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 5 p.m.; open public hearing, March 29, 1996, 8:30 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 5 p.m.; Leander B. Madoo, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4695, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Pulmonary-Allergy Drugs Advisory Committee, code 12545.

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 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. Those desiring to make formal presentations should notify the contact person before March 15, 1996, 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. On March 28, 1996, the committee will discuss Zeneca Pharmaceuticals' new drug application (NDA) 20–547 for Accolate® (zafirlukast) tablets. The proposed indication for Accolate® is as an oral anti-inflammatory agent for use in the prophylaxis and chronic treatment of asthma and as a first-line maintenance therapy in patients with asthma who are not adequately controlled by PRN β2-agonist alone. On March 29, 1996, the committee will discuss 3M Pharmaceuticals' NDA 20–503 for Epaq™, an albuterol metered-dose inhaler which is the first to utilize a hydrofluoroalkane propellent. The proposed indication is for treatment or prevention of bronchospasm in patients with reversible obstructive airway disease.

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 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 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 chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: February 16, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–4189 Filed 2–23–96; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting 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.

MEETING: The following advisory committee meeting is announced:

Science Board to the Food and Drug Administration

Date, time, and place. March 28 and 29, 1996, 8:30 a.m., Sheraton National Hotel, North Ballroom, 900 South Orme St. (Columbia Pike and Washington Blvd.), Arlington, VA.

Type of meeting and contact person. Open committee discussion, March 28, 1996, 8:30 a.m. to 2:30 p.m.; open public hearing, 2:30 p.m. to 3:30 p.m., unless public participation does not last that long; open committee discussion, 3:30 p.m. to 5 p.m.; open committee discussion, March 29, 1996, 8:30 a.m. to 10:30 a.m.; open public hearing 10:30 a.m. to 11:30 a.m., unless public participation does not last that long; open committee discussion, 11:30 a.m. to 1:30 p.m. For the March 28, 1996, agenda contact Susan Homire, Office of Science (HF–33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD, 20857, 301–827–3340; for the March 29, 1996, agenda contact Mary Gross, Office of External Affairs (HF–24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD, 20857, 301–827–3440; or, FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Science Board to the Food and Drug Administration, code 12603.

General function of the board. The board shall provide advice primarily to the agency's Senior Science Advisor, and, as needed, to the Commissioner and other appropriate officials on specific complex and technical issues as well as emerging issues within the scientific community in industry and academia. Additionally, the board will provide advice to the agency on keeping pace with technical and scientific evolutions in the fields of regulatory science; on formulating an appropriate research agenda; and on upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of agency-sponsored intramural and extramural scientific research programs.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the board. Those desiring to make formal presentations must notify the contact person before March 14, 1996, and submit a brief statement of the general nature of the evidence or arguments they wish to present, and the names and addresses of proposed participants. Each presenter will be limited in time and not all requests to speak may be able to be accommodated. All written statements submitted in a timely fashion will be provided to the board.

Open board discussion. On March 28, 1996, the board will discuss issues related to the safety in the testing of biomaterials used in products regulated by FDA; including strategies by which the agency can prepare for new developments in biomaterials science and the use of novel materials in device and medical implant products. On March 29, 1996, the board will discuss financial disclosure by clinical investigators. For further information on the agenda of this meeting see a document entitled ''Financial Disclosure by Clinical Investigators; Reopening of the Comment Period and Notice of Meeting,'' published elsewhere in this issue of the Federal Register.

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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.

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The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

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This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: February 16, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–4288 Filed 2–23–96; 8:45 am]

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National Institutes of Health

Alternative Medicine Program Advisory Council; Notice of Meeting

Pursuant to sec. 10(d) of the Federal Advisory Committee Act (FACA), as amended (Title 5, U.S.C. Appendix 2), notice is hereby given of the meeting of the Alternative Medicine Program Advisory Council on February 26, 1996, from 8 am to 5 pm and on February 27 from 8 am to 11 am in Conference Room 6, Building 31A, the National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland.