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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.
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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

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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:
Joint Meeting of the Nonprescription Drug Advisory Committee and the Arthritis Drugs Advisory Committee
Date, time, and place. October 9, 1996, 8:30 a.m., Holiday Inn--Bethesda, Versailles Ballrooms I, II, and III, 8120 Wisconsin Ave., Bethesda, MU.
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 5 p.m.; Kennerly K. Chapman or

Kathleen R. Reedy, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455, or e-mail ChapmanK@fda.cder.gov, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Nonprescription Drugs Advisory Committee, code 12541, or Arthritis Advisory Committee, code 12532. Please call the hotline for information concerning any possible changes.

General function of the committees. The Nonprescription Drugs Advisory Committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (OTC) (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases. The Arthritis Advisory Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in arthritic conditions.

Agenda--.Openpublic 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 October 2, 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. The committees will discuss new drug application (NDA) 20-373, St Ibuprofen (dexibuprofen, Sterling Winthrop/Bayer) 200-milligram caplet, indicated for the temporary relief of minor aches and pains associated with the common cold, headache, toothache, muscular aches, back ache, menstrual cramps, minor pain of arthritis, and for the temporary reduction of fever for OTC status.

Pulmonary-Allergy Drugs Advisory Committee

Date, time, and place. October 9, 1996, 9:30 a.m., Holiday Inn--Gaitlnersburg, Walker Ballroom, Two Montgomery Village Ave., Gaitlnersburg, MD.

Type of meeting and contact person. Open public hearing, 9:30 a.m. to 10:30 a.m., unless public participation does not last that long; open committee discussion, 10:30 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. Please call the hotline for information concerning any possible changes.

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 October 1, 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. The committee will discuss Genentech's clinical labeling supplement to modify the current prescribing information for Pulmozyme(R) (dornase alfa) pertaining to cystic fibrosis patients with forced vital capacity of the lung, less than 40 percent of predicted capacity.

Joint Meeting of the Nonprescription Drugs Advisory Committee and the Pulmonary-Allergy Drugs Advisory Committee

Date, time, and place. October 10 and 11, 1996, 8:30 a.m., Holiday

Inn--Bethesda, Versailles Ballrooms II and III, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open public hearing, October 10, 1996, 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 5 p.m.; open public hearing, October 11, 1996, 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 5 p.m.; Kennerly K. Chapman or 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), Nonprescription Drugs Advisory Committee, code 12541, Pulmonary-Allergy Drugs Advisory Committee, code 12545. Please call the hotline for information concerning any possible changes.

General function of the committees. The Nonprescription Drugs Advisory Committee reviews and evaluates available data concerning the safety and effectiveness of OTC (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases. The Pulmonary-Allergy Drugs Advisory 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 October 1, 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 October 10, 1996, the committees will

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jointly consider NDA 20-463, Nasalcrom(R) (Cromolyn Sodium Nasal Solution, United States Pharmacopeia) for OTC treatment of seasonal allergic rhinitis sponsored by McNeil Consumer Products Co. On October 11, 1996, the committees will jointly consider the prescription to OTC switch of NDA 19-589, Vancenase AQ(R) Nasal Spray (Beclomethasone Dipropionate) for the treatment of seasonal allergic rhinitis sponsored by Schering-Plough Pharmaceutical Co.

National Mammography Quality Assurance Advisory Committee

Date, time, and place. October 21 and 22, 1996, 9 a.m., and October 23, 1996, 8 a.m., Sheraton Reston Hotel, meeting rooms 1 and 2, 11810 Sunrise Valley Dr., Reston, VA. A limited number of overnight accommodations have been reserved at the Sheraton Reston Hotel. Attendees requiring overnight accommodations may contact the hotel at 703-620-9000 and reference the FDA committee meeting block. Reservations will be confirmed at the group rate based on availability.

'Type of meeting and contact person. Open public hearing, October 21, 1996, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 5 p.m.; open committee discussion, October 22, 1996, 9 a.m. to 5 p.m.; open committee discussion, October 23, 1996, 8 a.m. to 9 a.m.; open public hearing, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 5 p.m.; Charles K. Showalter, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-3332, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), National Mammography Quality Assurance Advisory Committee, code 12397. Please call the hotline for

information concerning any possible changes.

General function of the committee. The committee advises on developing appropriate quality standards and regulations for the use of mammography facilities.

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 October 7, 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 October 21 and 22, 1996, the committee will discuss regulation of interventional mammography under the Mammography Quality Standards Act (MQSA) of 1992. On October 23, 1996, the committee will discuss: (1) The request of the American Board of Certification in Radiology to be designated as eligible to certify interpreting physicians under the MQSA and (2) controversial areas of the proposed final regulations (see 61 FR 14856, April 3, 1996 (21 CFR part 900)). Copies of the proposed final regulations may be requested in writing from MQSA, c/o KRA Corp., 1010 Wayne Ave., suite 850, Silver Spring, MD, 20910, or FAX 301-495-9410.

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, 5600 Fishers Lane, rm. 12A-16, 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, 12420 Parklawn Dr., rm. 1-23, 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.

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This notice is issued under section 10(a)(1) and (a)(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: September 18, 1996.
Michael A. Friedman,
Deputy Commissioner for Operations.
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