

Dated: June 12, 1995.

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Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 95-15347 Filed 6-21-95; 8:45 am]

BILLING CODE 4160-01-F

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:

Gastrointestinal Drugs Advisory Committee

Date, time, and place. July 12, 1995, 9 a.m., Holiday Inn—Bethesda, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. 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.; Joan C. Standaert, Center for Drug Evaluation and Research (HFD-180), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 419-259-6211, or Valerie M. Mealy, Advisors and Consultants Staff (HFD-9), 301-443-4695, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC

area), Gastrointestinal Drugs Advisory Committee, code 12538.

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 gastrointestinal diseases.

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 June 30, 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 new drug application (NDA) 20-458, Lemmon Co., zinc acetate to be indicated for use in Wilson's disease. The advisory committee will also consider draft "Points to Consider" from the Division of Anti-Infective Drug Products on *Helicobacter pylori* studies to prevent peptic ulcer recurrence.

National Mammography Quality Assurance Advisory Committee

Date, time, and place. July 18 and 19, 1995, 9 a.m., Hyatt Regency—Bethesda, Cabinet-Judiciary Suite, One Bethesda Metro Center, Bethesda, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301-657-1234 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, July 18, 1995, 9 a.m. to 10 a.m., unless public participation does not last that long; open subcommittee discussions, 10 a.m. to 5 p.m.; open subcommittee discussions, July 19, 1995, 9 a.m. to 2 p.m.; open committee discussion, 2 p.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.

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 July 11, 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. On July 19, 1995, the committee will discuss the ongoing work of the three subcommittees: Access to Mammography Services, Physicists Availability, and Cost Benefit of Compliance.

Open subcommittee discussions. On July 18 and 19, 1995, the three subcommittees will meet concurrently. The subcommittees will discuss the ongoing work which is necessary to make the determinations and subsequently prepare the reports as mandated in the Mammography Quality Standards Act. Upon completion, the subcommittee reports will be reviewed by the committee prior to submission to the Secretary of Health and Human Services and Congress.

Ophthalmic Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. July 20 and 21, 1995, 8:30 a.m., Bethesda Pooks Hill Marriott, Congressional Ballroom, 5151 Pooks Hill Rd., Bethesda, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301-897-9400 and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Ed Rugenstein, Sociometrics, Inc., 301-608-2151. The availability of appropriate accommodations cannot be assured unless prior written notification is received.

Type of meeting and contact person. Open public hearing, July 20, 1995, 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, July 21, 1995, 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 m.; Sara M. Thornton, Center for Devices and Radiological Health