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Vol. 60 No. 162 Tuesday, August 22, 1995
Food and Drug Administration
Meetings: Advisory committees, panels, etc., 43599**

★ First Match

Food and Drug Administration

NOTICES

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Vol. 60 No. 162 Tuesday, August 22, 1995 p 43599 (Notice) 1/428
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Food and Drug Administration

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 information on FCA 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:

Generic Drugs Advisory Committee

Date, time, and place. September 6 and 7, 1995, 8:30 a.m., Holiday Inn-Gaithersburg, Two Montgomery Village Ave., Gaithersburg, MD.

Type of meeting and contact person. Open committee discussion, September 6, 1995, 8:30 a.m. to 11 a.m.; open public hearing,

11 a.m. to 12 m., unless public participation does not last that long; open committee discussion, 12 m. to 5 p.m.; open committee discussion, September 7, 1995, 8:30 a.m. to 12 m.; closed committee deliberations, 12 m. to 5 p.m.; Kimberly L. Topper or Angie Whitacre, 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), Generic Drugs Advisory Committee, code 12539.

General function of the committee. The committee gives advice on scientific and technical issues concerning the safety and effectiveness of human generic drug products for use in the treatment of a broad spectrum of human diseases and makes appropriate recommendations to the Secretary of Health and Human Services, the Assistant Secretary for Health, the Commissioner of Food and Drugs, and the Director of the Center for Drug Evaluation and Research. The committee may also review agency-sponsored intramural and extramural biomedical research programs in support of FDA's generic drugs regulatory responsibilities.

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 August 22, '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 September 6 and 7, 1995, the committee will review and advise on the status of Center for Drug Evaluation and Research (CDER) quality and performance initiatives related to formulation dissolution and bioequivalence. The committee will also discuss its relationship to, and interaction with, CDER's new Office of Pharmaceutical Sciences.

Closed committee deliberations. On September 7, 1995, the committee will discuss trade secret and/or confidential commercial information relevant to pending abbreviated new drug applications (ANDA's). This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Radiological Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. September 11, 1995, 9:30 a.m., Corporate Bldg., conference room 20B, 9200 Corporate Blvd., Rockville, MD. A limited number of overnight accommodations have been reserved at the Gaithersburg Marriott

---- page 43600 ----

Washingtonian Hotel, 9751 Washingtonian Blvd., Gaithersburg, MD. Attendees requiring overnight accommodations may contact the hotel at 301-590-0044 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, 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 12 m.; closed committee deliberations, 12 m. to 1 p.m.; open committee discussion, 1 p.m. to 4 p.m.; John C. Monahan, Center for Devices

and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1212, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Radiological Devices Panel, code 12526. -

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

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 September 6, 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 a draft guidance document entitled "Magnetic Resonance Imaging Guidance Update for Rate of Change of Gradient Fields." Single copies of the draft guidance are available from John C. Monahan (address above).

Closed committee deliberations. FDA staff will present to the committee trade secret and/or confidential commercial information regarding present and future FDA issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Neurological Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. September 15, 1995, 8 a.m., Corporate Bldg., ground floor conference room, 9200 Corporate Blvd., Rockville, MD. A limited number of overnight accommodations have been reserved at the Gaithersburg Marriott Washingtonian Hotel, 9751 Washingtonian Blvd., Gaithersburg, MD. Attendees requiring overnight accommodations may contact the hotel at 301-590-0044 and reference the FDA Panel meeting block. Reservations may 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 notification is received.

Type of meeting and contact person. Open public hearing, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 1:30 p.m.; closed committee deliberations, 1:30 p.m. to 4 p.m.; Jerilyn K. Glass, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8517, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Neurological Devices Panel, code 12513.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

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 September 4, 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 following topics: (1) Clinical perspectives on the use of balloon catheters, coils, and liquid occlusive devices for the treatment of aneurysms, arterio-venous malformations, or bleeding in the cerebrovascular circulation; and (2) research considerations when designing studies to evaluate these devices.

Closed committee deliberations. FDA staff will present to the committee trade secret and/or confidential commercial information regarding present and future FDA issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Immunology Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. September 21 and 22, 1995, 8 a.m., Holiday Inn-Gaithersburg, Walker and Whetstone Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301-948-8900 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, September 21, 1995, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 1:30 p.m.; open public hearing; 1:30 p.m. to 2:30 p.m., unless public participation does not last that long; open committee discussion, 2:30 p.m. to 6 p.m.; closed committee deliberations, September 22, 1995, 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.; Peter E. Maxim, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1293, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Immunology Devices Panel, code 12516.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

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 September 1, 1995, and submit a brief statement of

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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 general issues relating to the review of three premarket approval applications for: (1) An in situ hybridization assay to measure a prognostic marker in breast tumor tissues; (2) a serum tumor marker to aid in the detection of recurrence in Stage 2 and 3 breast cancer

patients; and (3) an assay to measure a urinary marker to aid in the detection of recurrence in bladder cancer patients.

Closed committee deliberations. FDA staff will present to the committee trade secret and/or confidential commercial information regarding pending or future device submissions. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Joint Meetings of Nonprescription Drugs Advisory Committee with Endocrinologic and Metabolic Drugs Advisory Committee, Drug Abuse Advisory Committee, and Gastrointestinal Drugs Advisory Committee

Date, time, and place. September 27 and 28, 1995, 8:30 a.m., and September 29, 1995, 3 p.m., conference rms. D and E, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, September 27, 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.; closed committee deliberations, 5 p.m. to 6 p.m.; open public hearing, September 28, 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 4 p.m.; open public hearing, 4 p.m. to 4:30 p.m., unless public participation does not last that long; open committee discussion, 4:30 p.m. to 6:30 p.m.; open committee discussion, September 29, 1995, 3 p.m. to 4 p.m.; Lee L. Zwanziger, Stephen Pollitt, or Liz Ortuzar, Center for Drug Evaluation and Research (HFD-9), 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.

General functions of the committees. The Nonprescription Drugs Advisory Committee reviews and evaluates data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases. The Endocrinologic and Metabolic Drugs Advisory Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in endocrine and metabolic disorders. The Drug Abuse Advisory Committee advises on the scientific and medical evaluation of information gathered by the Department of Health and Human Services and the Department of Justice on the safety, efficacy, and abuse potential of drugs and recommends actions to be taken on the marketing, investigation, and control of such drugs. The Gastrointestinal Drugs Advisory 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 September 19, 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 September 27, 1995, the Nonprescription Drugs Advisory Committee and some members of the Endocrinologic and Metabolic Drugs Advisory Committee will discuss public health issues relevant to cholesterol lowering regimens and data relevant to new drug application (NDA) 16-640 for cholestyramine (Questran(R))

powder) and NDA 19-669 for cholestyramine (Questran(R) Light with aspartame), sponsored by Bristol-Myers Squibb to switch the products from prescription to over-the-counter marketing status for use as adjunctive therapy to diet for the reduction of elevated serum cholesterol in patients with primary hypercholesterolemia (elevated low density lipoprotein (LDL) cholesterol) who do not respond adequately to diet. On September 28, 1995, the Nonprescription Drugs Advisory Committee and the Drug Abuse Advisory Committee will discuss data relevant to NDA 20-066 (Nicorette(R) 4 milligrams (mg) and NDA 18-612 (Nicorette(R) 2 mg) to switch nicotine polacrilex (Nicorette(R), SmithKline Beecham Consumer Healthcare Products) from prescription to over-the-counter status for use as an aid to smoking cessation for the relief of nicotine withdrawal symptoms. Later on September 28, 1995 the Nonprescription Drugs Advisory Committee and some members of the Gastrointestinal Drugs Advisory Committee will discuss data relevant to NDA 20-555 for nizatidine tablets, 75 mg, sponsored by Whitehall-Robins Healthcare to switch the product from prescription to over-the-counter status for the prevention of meal and beverage induced heartburn. During the afternoon of September 29, 1995, the Nonprescription Drugs Advisory Committee will discuss issues raised during the Public Hearing before the Commissioner on Over-The-Counter Drug Labeling held earlier during the same day.

Closed committee deliberations. On September 27, 1995, the Nonprescription Drugs Advisory Committee will discuss trade secret and/or confidential commercial information relevant to pending new drug applications. 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

---- page 43602 ----

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.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices;