1993 Federal Register (Vol 58) January - December
August
Vol. 58 No. 162 Tuesday, August 24,1993
Food and Drug Administration
Meetings: Advisory committees, panels, etc., << 44683>>

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Vol. 58 No. 162 Tuesday, August 24, 1993 p << 44683>> (Notice) 1/319

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.

MEETINGS: The following advisory committee meetings are announced:

Joint Meeting of the OTC Drugs Advisory Committee arid the Arthritis Advisory Committee

Date, time, and place. September 8, 1993, 8 a.m., Parklawn Bldg., conference rms. D and E, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Operi committee discussion, 8 a.m. to 11 a.m.; open public hearing, 11 a.m. to 12m., unless public participation does not last that long; open committee discussion, 12m. to 5 p.m.; closed comm ttee deliberations, 5 p.m. to 6 p.m.; Lee L. Zwanziger or Mae Brooks, Center for Drug Evaluation and Research (HFD-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4695.

General function of the committees. The OTC Drugs Advisory Committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of hurnan 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-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 31, 1393, 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 joint committee will discuss the relationship between alcohol and toxicities associated with OTC oral analgesic medications, except acetaminophen, in order to make recommendations on labeling to warn consumers of possible toxic effects of this combination. (On June 29, 1993, the OTC Drugs Advisory Committee discussed the relationship between alcohol and acetaminophen-induced liver toxicity (meeting announced in the Federal Register of May 17, 1993, 58 FR 28883 at 28885). The OTC Drugs Advisory Committee recommended that a warning be included in the labeling but that the agency defer action until. similar questions about OTC internal analgesic medications were discussed at an advisory·committee meeting). The joint committee will also discuss whether current data (i.e., case reports of gastrointestinal bleeding, pharmacokinetic, epidemiologic, or animal data) regarding the adverse effects of the use of alcohol with OTC analgesic drug products containing either aspirin, ibuprofen (or naproxen, should it become available over-the-counter) support the need for a label warning statement for products containing any or all of these ingredients; and if so, then which data support the need for a label warning statement for which ingredient. The agency is not aware of data concerning the adverse effects of the use of alcohol with other salicylates (i.e., carbaspirin calcium, choline salicylate, magnesium salicylate, and sodium salicylate) proposed by the agency to be generally recognized as safe and effective OTC analgesics. The committee will, however, discuss whether OTC products containing any or all of these ingredients should bear a similar warning statement, and, if so, what specific information the warning should contain (e.g., general warning versus organ-specific information, statement of risk, or other information) for each individual ingredient. Prior to the meeting, the agency may reformulate or add to the discussion topics listed above; final questions will be available on the morning of the meeting. The tentative final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products published in the Federal Register of November 16, 1988 (53 FR 46204). Additional new data submitted since that time will be considered by the committee members as they discuss whether the totality of the information warrants label revisions concerning the use of OTC dosages of internal analgesics with alcohol. The committee's recommendations will be considered by the agency in its preparation of the final monograph for OTC internal analgesic drug products. In addition, the committee will discuss further developments regarding new drug application (NDA) 20-204 to switch naproxen (Naprosyn(R), Syntex Corp.) from prescription to over-the-counter status.

Closed committee deliberations. The committee will review trade secret and/or confidential commercial information relevant to pending NDA's. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Gastrointestinal Drugs Advisory Committee

Date, time, and place. September 10, 1993, 9 a.m., Parklawn Bldg., conference rms. D and E, 5600 Fishers Lane, Rockville, 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; closed committee deliberations, 10 a.m. to 1 p.m.; Joan C. Standaert (HFD-180), 419-259-6211, or Valerie M. Mealy (HFD-9), Center for Drug Evaluation and Research, Food and Drug

Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4695.

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 August 30, 1993, 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.

Closed committee deliberations. The committee will discuss trade secret and/or confidential commercial information relevant to pending investigational new drug applications. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Oncologic Drugs Advisory Committee

Date, time, and place. September 23, 1993, 8 a.m., Parklawn Bldg., conference rms. D and E, 5600 Fishers Lane, Rockville, MD.

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 2:30 p.m.; closed committee deliberations, 2:30 p.m. to 5 p.m.; Adele S. Seifried, Center for Drug Evaluation and Research (HFD-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4695.

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 treatment of cancer.

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 17, 1993, 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: (1) Supplemental new drug application (NDA) 20-262, Taxol(R) for injection concentrate (paclitaxel, Bristol-Myers Squibb), for change of dose and schedule of administration to 175 mg/M†2 by 3 hour i.v. infusion from 135 mg/M†2 by 24 hour infusion; and (2) supplemental NDA 50-443, Blenoxane(R) (bleomycin sulfate, USP, Bristol-Myers Squibb), ''as a sclerosing agent for the treatment of malignant pleural effusions and for the prevention of recurrent pleural effusions.''

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

Blood Products Advisory Committee

Date, time, and place. September 23 and 24, 1993, 8:30 a.m., Holiday Inn Bethesda, Versailles Ballrooms III and IV, 8120

Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open committee discussion, September 23, 1993, 8:30 a.m. to 11:15 a.m.; open public hearing, 11:15 a.m. to 11:45 a.m., unless public participation does not last that long; open committee discussion, 11:45 a.m. to 5:45 p.m.; open public hearing, September 24, 1993, 8:30 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 2 p.m; closed committee deliberations, 2 p.m. to 3 p.m.; Linda A. Smallwood, Office of Blood Research and Review, Center for Biologics Evaluation and Research (HFM-300), Food and Drug Administration, 1401 Rockville Pike, Bethesda, MD 20852, 301-594-6700.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness, and appropriate use of blood products intended for use in the diagnosis, prevention, or treatment of human 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 16, 1993, 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 23, 1993, the committee will review and discuss the product license application for Respiratory Syncytial Virus Immune Globulin Intravenous (Human) submitted by the Massachusetts Public Health Biologic Laboratories to reduce the incidence of severe Respiratory Syncytial Virus infection in infants with premature gestation and children with chronic pulmonary disease. In the afternoon, the committee will review the report of the FDA contract study on Increasing the Safety of the Blood Supply by Screening More Effectively. On September 24, 1993, the committee will hear presentations on Blood Product Transmission of Hepatitis A and Other Non-Enveloped Viruses, and review the report of the Scientific Site Visit for the Laboratory of Hemostasis, Division of Hematology, Office of Blood and Blood Research, Center for Biologics Evaluation and Research.

Closed committee deliberations. The committee will discuss the intramural scientific program. This portion of the meeting will be closed to prevent disclosure of personal information concerning individuals associated with the research program, disclosure of which would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)).

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 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, with the concurrence of the Chief Counsel, 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 desiynated 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; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, notably deliberative session to formulate advice and recommendations to the agency on matters that do not independently justify closing.

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: August 18, 1993.

Jane E. Henney,
Deputy Commissioner for Operations.

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The Contents entry for this article reads as follows:

Meetings:
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