1994 Federal Register (Vol 59) January - December
October
Vol. 59 No. 207 Thursday, October 27,1994
Food and Drug Administration
Meetings: Advisory committees, panels, etc., 53995

Meetings: Advisory committees, panels, etc., 53995

Vol. 59 No. 207 Thursday, October 27, 1994 p 53995 (Notice) 1/178

Advisory Committee Meeting; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

.....

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of the joint meeting of the Nonprescription Drugs and the Pulmonary-Allergy Drugs Advisory Committees, which was announced in the Federal Register of July 7, 1994 (59 FR 34847). The amendment is being made to add an additional topic to the agenda of the open session and to add a closed session for the Nonprescription Drugs Advisory Committee. There are no other changes. This amendment will be announced at the beginning of the open portion of the meeting.

FOR FURTHER INFORMATION CONTACT: Lee L. Zwanziger or Leander B. Madoo, Center for Drug Evaluation and Research (HFD-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-463-5455.

SUPPLEMENTARY INFORMATION: In the Federal Register of July 7, 1994, FDA announced that a joint meeting of the Nonprescription Drugs and the Pulmonary-Allergy Drugs Advisory Committees would be held on November 14, 1994, to be extended to November 15, 1994, if sufficient interest in participation was expressed. On page 34847, in column 1, the ''Type of meeting and contact person'' portion of the meeting is amended as follows:

Type of meeting and contact person. Open committee discussion, November 14, 1994, 8:30 a.m. to 4 p.m.; open public hearing, 4 p.m. to 5 p.m., unless public participation does not last that long; closed committee deliberations for Nonprescription Drugs Advisory Committee only, 5 p.m. to 5:30 p.m.; open committee discussion, November 15, 1994, 8:30 a.m. to 4 p.m.; Lee L. Zwanziger or Leander B. Madoo, Center for Drug Evaluation and Research (HFD-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4695.

On page 34847, in column 2, the ''Open committee discussion'' portion of this meeting is amended as follows:

Open committee discussion. On November 14, 1994, possibly extended to November 15, 1994, the committees will jointly discuss over-the-counter (OTC) drug products for the treatment of asthma

and will address topics such as: (1) OTC bronchodilator drug products currently available and possible pending changes in their marketing status; (2) whether there is a population for which OTC antiasthma drug products are appropriate; (3) the general question of whether antiasthma drug products should be available OTC; (4) antiasthma drug products currently available by prescription only that could be considered for OTC status; and (5) data requirements necessary to support conversion of prescription antiasthma drug products to OTC status. Public comments are available for inspection in docket no. 94N-0232 at the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. If the meeting is extended to November 15, 1994, the committees will hear a report by FDA personnel of a meta-analysis of data on the use of antihistamines in the common cold.

After the ''open committee discussion'' portion, a ''closed committee deliberations'' portion is added as follows:

Closed committee deliberations. The Nonprescription Drugs Advisory 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)).

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.

Ary 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 purpcses; 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, deliberation 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: October 20, 1994

Linda A. Suydam,
Interim Deputy Commissioner for Operations

[FR Doc. 94-26672 Filed 10-26-94; 8:45 am]
BILLING CODE 4160-01-F

The Contents entry for this article reads as follows:

Meetings:
  Advisory committees, panels, etc., 53995

1994 Federal Register (Vol 59) January - December
July
Vol. 59 No. 129 Thursday, July 7,1994
Food and Drug Administration
Meetings: Advisory committees, panels, etc., 34847

NOTICES

Meetings: Advisory committees, panels, etc., 34847

Vol. 59 No. 129 Thursday, July 7, 1994 p 34847 (Notice) 1/134

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming joint meeting of public advisory committees 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.

MEETING: The following advisory committee meeting is announced:

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

Date, time, and place. November 14, 1994, 8:30 a.m., Parklawn Bldg., conference rms. G through J, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open committee discussion, 8:30 a.m. to 4 p.m.; open public hearing, 4 p.m. to 5 p.m., unless public participation does not last that long; the agency anticipates that the meeting will last only 1 day, but if there is sufficient interest in participation, the meeting will be extended an additional day at the discretion of the chairperson; Lee L. Zwanziger or Leander B. Madoo, 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 Nonprescription 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 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 committees. Those desiring to make formal presentations should notify a contact person before September 30, 1994, 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 jointly discuss over-the-counter (OTC) drug products for the treatment of asthma and will address topics such as: (1) OTC bronchodilator drug products currently available and possible pending changes in their marketing status; (2) whether there is a population for which OTC antiasthma drug products are appropriate; (3) the general question of whether antiasthma drug products should be available OTC; (4) antiasthma drug products currently available by prescription only that could be considered for OTC status; and (5) data requirements necessary to support conversion of prescription anfiasthma drug products to OTC status. Public comments are available for inspection in docket no. 94N-0232 at the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

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: June 30,1994.

Linda A. Suydam,
Interim Deputy Commissioner for Operations.

[FR Doc. 94-16365 Filed 7-6-94; 8:45 am]
BILLING CODE 4160-01-F

.....

The Contents entry for this article reads as follows:

Meetings:
Advisory committees, panels, etc., 34847