

§ 13.30

the director's position, which relate to the issues involved in the hearing. *Files* means the principal files in the center in which documents relating to the issues in the hearing are ordinarily kept, e.g., the food additive master file and the food additive petition in the case of issues concerning a food additive, or the new drug application in the case of issues concerning a new drug. Internal memoranda reflecting the deliberative process, and attorney work product and material prepared specifically for use in connection with the hearing, are not required to be submitted;

(4) All other documentary information relied on; and

(5) A signed statement that, to the best of the director's knowledge and belief, the submission complies with this section.

(b) Within the time prescribed in the notice of hearing published under §13.5, each participant shall submit to the Division of Dockets Management all information specified in paragraph (a)(2) through (5) of this section and any objections that the administrative record filed under paragraph (a)(1) of this section is incomplete. With respect to the information specified in paragraph (a)(3) of this section, participants are to exercise reasonable diligence in identifying documents in files comparable to those described in that paragraph.

(c) The submissions required by paragraphs (a) and (b) of this section may be supplemented later in the proceeding, with the approval of the Board, on a showing that the views of the persons or the material contained in the supplement was not known or reasonably available when the initial submission was made or that the relevance of the views of the persons or the material contained in the supplement could not reasonably have been foreseen.

(d) The failure to comply substantially and in good faith with this section in the case of a participant constitutes a waiver of the right to participate further in the hearing and in the case of a party constitutes a waiver of the right to a hearing.

(e) The Chairman rules on questions relating to this section. Any partici-

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pant dissatisfied with a ruling may petition the Commissioner for interlocutory review.

[44 FR 22348, Apr. 13, 1979, as amended at 50 FR 8994, Mar. 6, 1985; 54 FR 9035, Mar. 3, 1989]

§ 13.30 Proceedings of a Board.

(a) The purpose of a Board is to review medical, scientific, and technical issues fairly and expeditiously. The proceedings of a Board are conducted as a scientific inquiry rather than a legal trial.

(b) A Board may not hold its first hearing until after all participants have submitted the information required by §13.25.

(c) The Chairman calls the first hearing of the Board. Notice of the time and location of the first hearing is to be published at least 15 days in advance and the hearing will be open to the public. All participants will have an opportunity at the first hearing to make an oral presentation of the information and views which in their opinion are pertinent to the resolution of the issues being considered by a Board. A participant's presentation may be made by more than one person. The Chairman determines the order of the presentation. Participants may not interrupt a presentation, but members of the Board may ask questions. At the conclusion of a presentation, each of the other participants may briefly comment on the presentation and may request that the Board conduct further questioning on specified matters. Members of the Board may then ask further questions. Any other participant may be permitted to ask questions if the Chairman determines that it will help resolve the issues.

(d) The hearing is informal and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views may be made or considered, but other participants may comment upon or rebut all such information and views. No participant may interrupt the presentation of another participant for any reason.

(e) Within the time specified by the Board after its first hearing, participants may submit written rebuttal information and views in accordance with §13.20. The Chairman will then

schedule a second hearing, if requested and justified by a participant. A second hearing, and any subsequent hearing, will be called only if the Chairman concludes that it is needed to fully and fairly present information that cannot otherwise adequately be considered and to properly resolve the issues. Notice of the time and location of any hearing is to be published at least 15 days in advance. The hearing is open to the public.

(f) A Board may consult with any person who it concludes may have information or views relevant to the issues.

(1) The consultation may occur only at an announced hearing of a Board. Participants have the right to suggest or, with the permission of the Chairman, ask questions of the consultant and present rebuttal information and views, as provided in paragraphs (c) and (d) of this section except that written statements may be submitted to the Board with the consent of all participants.

(2) A participant may submit a request that the Board consult with a specific person who may have information or views relevant to the issues. The request will state why the person should be consulted and why the person's views cannot be furnished to the Board by means other than having FDA arrange for the person's appearance. The Board may, in its discretion, grant or deny the request.

(g) All hearings are to be transcribed. All hearings are open to the public, except that a hearing under §10.20(j)(3) is closed to all persons except those persons making and participating in the presentation and Federal Government executive branch employees and special Government employees. At least a majority of Board members are to be present at every hearing. The executive sessions of a Board, during which a Board deliberates on the issues, are to be closed and are not transcribed. All members of the Board shall vote on the report of the Board.

(h) All legal questions are to be referred to the Chief counsel for FDA for resolution. The Chief Counsel's advice on any matter of procedure or legal authority is to be transmitted in writing

and made a part of the record or presented in open session and transcribed.

(i) At the conclusion of all public hearings the Board will announce that the record is closed to receiving information. The Board will provide an opportunity for participants to submit written statements of their positions, with proposed findings and conclusions, and may in its discretion, provide an opportunity for participants to summarize their positions orally.

(j) The Board will prepare a decision on all issues. The decision is to include specific findings and references supporting and explaining the Board's conclusions, and a detailed statement of the reasoning on which the conclusions are based. Any member of the Board may file a separate report stating additional or dissenting views.

Subpart C—Records of a Hearing Before a Board

§13.40 Administrative record of a Board.

(a) The administrative record of a hearing before a Board consists of the following:

(1) All relevant FEDERAL REGISTER notices.

(2) All written submissions under §13.20.

(3) The transcripts of all hearings of the Board.

(4) The initial decision of the Board.

(b) The record of the administrative proceeding is closed—

(1) Relevant to receiving information and data, at the time specified in §13.30(i); and

(2) Relevant to pleadings, at the time specified in §13.30(i) for filing a written statement of position with proposed findings and conclusions.

(c) The Board may, in its discretion, reopen the record to receive further evidence at any time before filing an initial decision.

§13.45 Examination of administrative record.

(a) The availability for public examination and copying of each document which is a part of the administrative record of the hearing is governed by §10.20(j). Each document available for public examination or copying is