

Food and Drug Administration, HHS

§ 13.5

(e) Notice of the Commissioner's decision will be published in the FEDERAL REGISTER, or the Commissioner may publish the decision when it is of widespread interest.

§ 12.139 Reconsideration and stay of action.

Following notice or publication of the final decisions, a participant may petition the Commissioner for reconsideration of any part or all of the decision under § 10.33 or may petition for a stay of the decision under § 10.35.

Subpart H—Judicial Review

§ 12.140 Review by the courts.

(a) The Commissioner's final decision constitutes final agency action from which a participant may petition for judicial review under the statutes governing the matter involved. Before requesting an order from a court for a stay of action pending review, a participant shall first submit a petition for a stay of action under § 10.35.

(b) Under 28 U.S.C. 2112(a), FDA will request consolidation of all petitions related to a particular matter.

§ 12.159 Copies of petitions for judicial review.

The Chief Counsel for FDA has been designated by the Secretary as the officer on whom copies of petitions of judicial review are to be served. This officer is responsible for filing the record on which the final decision is based. The record of the proceeding is certified by the Commissioner.

PART 13—PUBLIC HEARING BEFORE A PUBLIC BOARD OF INQUIRY

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SOURCE: 44 FR 22348, Apr. 13, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 13.1 Scope.

The procedures in this part apply when—

(a) The Commissioner concludes, as a matter of discretion, that it is in the public interest to hold a public hearing before a Public Board of Inquiry (*Board*) with respect to any matter before FDA;

(b) Under specific sections of this chapter a matter before FDA is subject to a hearing before a Board; or

(c) Under § 12.32, a person who has a right to an opportunity for a formal evidentiary public hearing waives that opportunity and requests that a Board act as an administrative law tribunal concerning the matters involved, and the Commissioner decides to accept this request.

§ 13.5 Notice of a hearing before a Board.

If the Commissioner determines that a Board should be established to conduct a hearing on any matter, a notice of hearing will be published in the FEDERAL REGISTER setting forth the following information:

(a) If the hearing is under § 13.1 (a) or (b), all applicable information described in § 12.32(e).

(1) Any written document that is to be the subject matter of the hearing will be published as a part of the notice, or the notice will refer to it if the document has already been published in the FEDERAL REGISTER or state that the document is available from the Division of Dockets Management or an agency employee designated in the notice.

(2) For purposes of a hearing under § 13.1 (a) or (b), all participants who file

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a notice of participation under § 12.32(e)(6)(ii) are deemed to be parties and entitled to participate in selection of the Board under § 13.15(b).

(b) If the hearing is in lieu of a formal evidentiary hearing, as provided in § 13.1(c), all of the information described in § 12.32(e).

[44 FR 22348, Apr. 13, 1979, as amended at 47 FR 26375, June 18, 1982]

§ 13.10 Members of a Board.

(a) All members of a Board are to have medical, technical, scientific, or other qualifications relevant to the issues to be considered, are subject to the conflict of interest rules applicable to special Government employees, and are to be free from bias or prejudice concerning the issues involved. A member of a Board may be a full-time or part-time Federal Government employee or may serve on an FDA advisory committee but, except with the agreement of all parties, may not currently be a full-time or part-time employee of FDA or otherwise act as a special Government employee of FDA.

(b) Within 30 days of publication of the notice of hearing, the director of the center of FDA responsible for a matter before a Board, the other parties to the proceeding, and any person whose petition was granted and is the subject of the hearing, shall each submit to the Division of Dockets Management the names and full curricula vitae of five nominees for members of the Board. Nominations are to state that the nominee is aware of the nomination, is interested in becoming a member of the Board, and appears to have no conflict of interest.

(1) Any two or more persons entitled to nominate members may agree upon a joint list of five qualified nominees.

(2) The lists of nominees must be submitted to the persons entitled to submit a list of nominees under this paragraph but not to all participants. Within 10 days of receipt of the lists of nominees, such persons may submit comments to the Division of Dockets Management on whether the nominees of the other persons meet the criteria established in paragraph (a) of this section. A person submitting comments to the Division of Dockets Management

shall submit them to all persons entitled to submit a list of nominees.

(3) The lists of nominees and comments on them are to be held in confidence by the Division of Dockets Management as part of the administrative record of the proceeding and are not to be made available for public disclosure, and all persons who submit or receive them shall similarly hold them in confidence. This portion of the administrative record remains confidential but is available for judicial review in the event that it becomes relevant to any issue before a court.

(c) After reviewing the lists of nominees and any comments, the Commissioner will choose three qualified persons as members of a Board. One member will be from the lists of nominees submitted by the director of the center and by any person whose petition was granted and is the subject of the hearing. The second will be from the lists of nominees submitted by the other parties. The Commissioner may choose the third member from any source. That member is the Chairman of the Board.

(1) If the Commissioner is unable to find a qualified person with no conflict of interest from among a list of nominees or if additional information is needed, the Commissioner will request the submission of the required additional nominees or information.

(2) If a person fails to submit a list of nominees as required by paragraph (b) of this section, the Commissioner may choose a qualified member without further consultation with that person.

(3) The Commissioner will announce the members of a Board by filing a memorandum in the record of the proceeding and sending a copy to all participants.

(d) Instead of using the selection method in paragraphs (b) and (c) of this section, the director of the center, the other parties to the proceeding, and any person whose petition was granted and is the subject of the hearing, may, with the approval of the Commissioner, agree that a standing advisory committee listed in § 14.80 constitutes the Board for a particular proceeding, or that another procedure is to be used for selection of the members of the Board, or that the Board consists of a larger number of members.