

PART 13—PUBLIC HEARING BEFORE A PUBLIC BOARD OF INQUIRY

Subpart A—General Provisions

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

EDITORIAL NOTE: Nomenclature changes to part 13 appear at 88 FR 45065, July 14, 2023.

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 con-

duct 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 Dockets Management Staff or an agency employee designated in the notice.

(2) For purposes of a hearing under § 13.1 (a) or (b), all participants who file 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 Dockets Management Staff the names and full curricula vitae of five nominees for members of the Board. Nominations are to state that