

§ 15.1

AUTHORITY: 5 U.S.C. 553; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–393, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b–263n, 264.

SOURCE: 44 FR 22366, Apr. 13, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 15.1 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 permit persons to present information and views at a public hearing on any matter pending before the Food and Drug Administration.

(b) The act or regulation specifically provides for a public hearing before the Commissioner on a matter, e.g., § 330.10(a)(8) relating to over-the-counter drugs and sections 520 (b) and (f)(1)(B), and 521 of the act relating to proposals to allow persons to order custom devices, to proposed device good manufacturing practice regulations, and to proposed exemptions from pre-emption of State and local device requirements under § 808.25(e).

(c) A person who has right to an opportunity for a formal evidentiary public hearing under part 12 waives that opportunity and instead requests under § 12.32 a public hearing before the Commissioner, and the Commissioner, as a matter of discretion, accepts the request.

Subpart B—Procedures for Public Hearing Before the Commissioner

§ 15.20 Notice of a public hearing before the Commissioner.

(a) If the Commissioner determines that a public hearing should be held on a matter, the Commissioner will publish a notice of hearing in the FEDERAL REGISTER setting forth the following information:

(1) If the hearing is under § 15.1 (a) or (b), the notice will state the following:

(i) The purpose of the hearing and the subject matter to be considered. If a written document is to be the subject matter of the hearing, it will be published as part of the notice, or reference made to it if it has already been published in the FEDERAL REGISTER, or

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the notice will state that the document is available from an agency office identified in the notice.

(ii) The time, date, and place of the hearing, or a statement that the information will be contained in a subsequent notice.

(2) If the hearing is in lieu of a formal evidentiary public hearing under § 15.1(c), all of the information described in § 12.32(e).

(b) The scope of the hearing is determined by the notice of hearing and any regulation under which the hearing is held. If a regulation, e.g., § 330.10(a)(10), limits a hearing to review of an existing administrative record, information not already in the record may not be considered at the hearing.

(c) The notice of hearing may require participants to submit the text of their presentations in advance of the hearing if the Commissioner determines that advance submissions are necessary for the panel to formulate useful questions to be posed at the hearing under § 15.30(e). The notice may provide for the submission of a comprehensive outline as an alternative to the submission of the text if the Commissioner determines that submission of an outline will be sufficient.

[44 FR 22366, Apr. 13, 1979, as amended at 47 FR 26375, June 18, 1982]

§ 15.21 Notice of participation; schedule for hearing.

(a) The notice of hearing will provide persons an opportunity to file a written notice of participation with the Division of Dockets Management within a specified period of time containing the information specified in the notice, e.g., name of participant, address, phone number, affiliation, if any, topic of presentation and approximate amount of time requested for the presentation. If the public interest requires, e.g., a hearing is to be conducted within a short period of time or is to be primarily attended by individuals without an organizational affiliation, the notice may name a specific FDA employee and telephone number to whom an oral notice of participation may be given or provide for submitting notices of participation at the time of the hearing. A written or oral notice of participation must be received by the