

§ 15.21

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

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designated person by the close of business of the day specified in the notice.

(b) Promptly after expiration of the time for filing a notice, the Commissioner will determine the amount of time allotted to each person and the approximate time that oral presentation is scheduled to begin. If more than one hearing is held on the same subject, a person will ordinarily be allotted time for a presentation at only one hearing.

(c) Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and to request time for a joint presentation. The Commissioner may require joint presentations by persons with common interests.

(d) The Commissioner will prepare a hearing schedule showing the persons making oral presentations and the time allotted to each person, which will be filed with the Division of Dockets Management and mailed or telephoned before the hearing to each participant.

(e) The hearing schedule will state whether participants must be present by a specified time to be sure to be heard in case the absence of participants advances the schedule.

§ 15.25 Written submissions.

A person may submit information or views on the subject of the hearing in writing to the Division of Dockets Management, under §10.20. The record of the hearing will remain open for 15 days after the hearing is held for any additional written submissions, unless the notice of the hearing specifies otherwise or the presiding officer rules otherwise.

§ 15.30 Conduct of a public hearing before the Commissioner.

(a) The Commissioner or a designee may preside at the hearing, except where a regulation provides that the Commissioner will preside personally. The presiding officer may be accompanied by other FDA employees or other Federal Government employees designated by the Commissioner, who may serve as a panel in conducting the hearing.

(b) The hearing will be transcribed.