making oral presentations and the time alloted to each person, which will be filed with the Dockets Management Branch 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 Dockets Management Branch, 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.

(c) Persons may use their alloted time in whatever way they wish, consistent with a reasonable and orderly hearing. A person may be accompanied by any number of additional persons, and may present any written information or views for inclusion in the record of the hearing, subject to the requirements of §15.25. The presiding officer may allot additional time to any person when the officer concludes that it is in the public interest, but may not reduce the time allotted for any person without the consent of the person.

(d) If a person is not present at the time specified for the presentation, the persons following will appear in order, with adjustments for those appearing at their scheduled time. An attempt will be made to hear any person who is late at the conclusion of the hearing. Other interested persons attending the hearing who did not request an opportunity to make an oral presentation will be given an opportunity to make an oral presentation at the conclusion of the hearing, in the discretion of the presiding officer, to the extent that time permits.

(e) The presiding officer and any other persons serving on a panel may question any person during or at the conclusion of the presentation. No other person attending the hearing may question a person making a presentation. The presiding officer may, as a matter of discretion, permit questions to be submitted to the presiding officer or panel for response by them or by persons attending the hearing.

(f) The hearing is informal in nature, 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 at any hearing for any reason.

(g) The hearing may end early only if all persons scheduled for a later presentation have already appeared or it is past the time specified in the hearing schedule, under §15.21(e), by which participants must be present.

(h) The Commissioner or the presiding officer may, under §10.19, suspend, modify, or waive any provision of this part.

Subpart C—Records of a Public Hearing Before the Commissioner

§15.40 Administrative record.

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

(1) All relevant FEDERAL REGISTER notices, including any documents to which they refer.

(2) All written submissions under §15.25.

(3) The transcript of the oral hearing.

(b) The record of the administrative proceeding will be closed at the time specified in §15.25.

§15.45 Examination of administrative record.

Section 10.20(j) governs the availability for public examination and copying

of each document in the administrative record of the hearing

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

Subpart A—General Provisions

Sec.
16.1 Scope.
16.5 Inapplicability and limited applicability.

Subpart B—Initiation of Proceedings

16.22 Initiation of regulatory hearing.
16.24 Regulatory hearing required by the act or a regulation.
16.26 Denial of hearing and summary decision.

Subpart C—Commissioner and Presiding Officer

16.40 Commissioner.
16.42 Presiding officer.
16.44 Communication to presiding officer and Commissioner.

Subpart D—Procedures for Regulatory Hearing

16.60 Hearing procedure.
16.62 Right to counsel.

Subpart E—Administrative Record and Decision

16.80 Administrative record of a regulatory hearing.
16.85 Examination of administrative record.
16.95 Administrative decision and record for decision.

Subpart F—Reconsideration and Stay

16.119 Reconsideration and stay of action.

Subpart G—Judicial Review

16.120 Judicial review.

AUTHORITY: 21 U.S.C. 40–41, 141–149, 321–394, 467f, 679, 821, 1034; 42 U.S.C. 201–262, 263b, 364; 15 U.S.C. 1451–1461, 28 U.S.C. 2112.

SOURCE: 44 FR 22367, Apr. 13, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 16.1 Scope.

The procedures in this part apply when:

(a) The Commissioner is considering any regulatory action, including a refusal to act, and concludes, as a matter of discretion, on the Commissioner's initiative or at the suggestion of any person, to offer an opportunity for a regulatory hearing to obtain additional information before making a decision or taking action.

(b) The act or a regulation provides a person with an opportunity for a hearing on a regulatory action, including proposed action, and the act or a regulation either specifically provides an opportunity for a regulatory hearing under this part or provides an opportunity for a hearing for which no procedures are specified by regulation. Listed below are the statutory and regulatory provisions under which regulatory hearings are available:

(1) Statutory provisions:

Section 304(g) of the act relating to the administrative detention of devices (see § 800.55(g) of this chapter).

Section 515(e)(1) of the act relating to the proposed withdrawal of approval of a device premarket approval application.

Section 515(e)(3) of the act relating to the temporary suspension of approval of a premarket approval application.

Section 515(f)(6) of the act relating to a proposed order revoking a device product development protocol or declaring a protocol not completed.

Section 515(f)(7) of the act relating to revocation of a notice of completion of a product development protocol.

Section 516 of the act relating to a proposed banned device regulations (see § 895.21(d) of this chapter).

Section 518(b) of the act relating to a determination that a device is subject to a repair, replacement, or refund order or that a correction plan, or revised correction plan, submitted by a manufacturer, importer, or distributor is inadequate.

Section 518(e) of the act relating to a cease distribution and notification order or mandatory recall order concerning a medical device for human use.

Section 520(f)(2)(D) of the act relating to exemptions or variances from device current good manufacturing practice requirements (see § 820.1(d)).

Section 520(g)(4) and (g)(5) of the act relating to disapproval and withdrawal of approval of an application from an investigational device exemption (see §§ 812.19(c), 812.30(c), 813.30(d), and 813.35(c) of this chapter).

(2) Regulatory provisions: