

§ 15.40

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

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PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

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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:

- §56.121(a), relating to disqualifying an institutional review board or an institution.
- §71.37(a), relating to use of food containing a color additive.
- §80.31(b), relating to refusal to certify a batch of a color additive.

- §80.34(b), relating to suspension of certification service for a color additive.
 - §99.401(c), relating to a due diligence determination concerning the conduct of studies necessary for a supplemental application for a new use of a drug or device.
 - §130.17(1), relating to a temporary permit to vary from a food standard.
 - §170.17(b), relating to use of food containing an investigational food additive.
 - §202.1(j)(5), relating to approval of prescription drug advertisements.
 - §312.70, relating to whether an investigator is entitled to receive investigational new drugs.
 - §312.70(d) and 312.44, relating to termination of an IND for a sponsor.
 - §312.160(b), relating to termination of an IND for tests in vitro and in laboratory research animals for a sponsor.
 - §511.1(b)(5), relating to use of food containing an investigational new animal drug.
 - §511.1(c)(1), relating to termination of an INAD for an investigator.
 - §511.1(c) (4) and (d), relating to termination of an INAD for a sponsor.
 - §814.46(c) relating to withdrawal of approval of a device premarket approval application.
 - §900.7, relating to approval, reapproval, or withdrawal of approval of mammography accreditation bodies or rejection of a proposed fee for accreditation.
 - §900.14, relating to suspension or revocation of a mammography certificate.
 - §900.25, relating to approval or withdrawal of approval of certification agencies.
 - §1003.11(a)(3), relating to the failure of an electronic product to comply with an applicable standard or to a defect in an electronic product.
 - §1003.31(d), relating to denial of an exemption from notification requirements for an electronic product which fails to comply with an applicable standard or has a defect.
 - §1004.6, relating to plan for repurchase, repair, or replacement of an electronic product.
 - §1210.30, relating to denial, suspension, or revocation of a permit under the Federal Import Milk Act.
 - §1240.63(c)(3), relating to a written order to cause an animal to be placed in quarantine or to cause an animal to be destroyed.
 - §1270.15(e), relating to the retention, recall, and destruction of human tissue.
- [44 FR 22367, Apr. 13, 1979, as amended at 45 FR 3750, Jan 18, 1980; 45 FR 10332, Feb. 15, 1980; 46 FR 8975, Jan. 27, 1981; 46 FR 14340, Feb. 27, 1981; 51 FR 26364, July 22, 1986; 54 FR 9037, Mar. 3, 1989; 57 FR 58403, Dec. 10, 1992; 58 FR 65520, Dec. 14, 1993; 62 FR 40444, July 29, 1997; 62 FR 55976, Oct. 28, 1997; 63 FR 26697, May 13, 1998; 63 FR 64581, Nov. 20, 1998; 67 FR 5467, Feb. 6, 2002; 68 FR 62368, Nov. 4, 2003]