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

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 304(h) of the act relating to the administrative detention of food for human or animal consumption (see part 1, subpart k 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.
§ 1270.43(e), relating to the retention, recall, and destruction of human tissue.
§ 1271.440(e) relating to the retention, recall, and destruction of human cells, tissues, and cellular and tissue-based products (HCT/Ps), and/or the cessation of manufacturing HCT/Ps.

[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; 69 FR 31705, June 4, 2004; 69 FR 68680, Nov. 24, 2004; 73 FR 49942, Aug. 25, 2008; 73 FR 51919, Sept. 8, 2008]

§ 16.5 Inapplicability and limited applicability.

(a) This part does not apply to the following:

(1) Informal presentation of views before reporting a criminal violation under section 305 of the act and section 5 of the Federal Import Milk Act and § 1210.31.

(2) A hearing on a refusal of admission of a food, drug, device, or cosmetic under section 801(a) of the act and § 1.94, or of an electronic product under section 360(a) of the Public Health Service Act and § 1005.20.

(3) Factory inspections, recalls (except mandatory recalls of medical devices intended for human use), regulatory letters, and similar compliance activities related to law enforcement.

(4) A hearing on an order for relabeling, diversion, or destruction of shell eggs under section 361 of the Public Health Service Act (42 U.S.C. 264) and §§ 101.17(h) and 115.50 of this chapter.

(5) A hearing on an order for diversion or destruction of shell eggs under section 361 of the Public Health Service Act (42 U.S.C. 264), and § 118.12 of this chapter.

(b) If a regulation provides a person with an opportunity for hearing and specifies some procedures for the hearing but not a comprehensive set of procedures, the procedures in this part apply to the extent that they are supplementary and not in conflict with the other procedures specified for the hearing. Thus, the procedures in subpart A of part 108 relating to emergency permit control are supplemented by the nonconflicting procedures in this part, e.g., the right to counsel, public notice of the hearing, reconsideration and stay, and judicial review.

[44 FR 22367, Apr. 13, 1979, as amended at 57 FR 58403, Dec. 10, 1992; 65 FR 76110, Dec. 5, 2000; 74 FR 33095, July 9, 2009]

Subpart B—Initiation of Proceedings

§ 16.22 Initiation of regulatory hearing.

(a) A regulatory hearing is initiated by a notice of opportunity for hearing from FDA. The notice will—

(1) Be sent by mail, telegram, telex, personal delivery, or any other mode of written communication;