

Food and Drug Administration, HHS

§ 16.22

- §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.
- §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.
- §1270.15(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]

§ 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.

(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]

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;

(2) Specify the facts and the action that are the subject of the opportunity for a hearing;

(3) State that the notice of opportunity for hearing and the hearing are governed by this part; and

(4) State the time within which a hearing may be requested, and state