

§ 16.5

21 CFR Ch. I (4–1–23 Edition)

FDA including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products.

§ 814.46(c) relating to withdrawal of approval of a device premarket approval application.

§ 822.7(a)(3), relating to an order to conduct postmarket surveillance of a medical device under section 522 of the act.

§ 830.130, relating to suspension or revocation of the accreditation of an issuing agency.

§ 895.30(c), regarding a proposed regulation to ban a medical device with a special effective date.

§ 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.

§ 1107.1(d), relating to rescission of an exemption from the requirement of demonstrating substantial equivalence for a tobacco product.

§ 1107.50, relating to rescission of an order finding a tobacco product substantially equivalent.

§ 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]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 16.1, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.

§ 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;