

§ 12.22

21 CFR Ch. I (4–1–25 Edition)

351(a) of the Public Health Service Act, may be initiated—

(1) By the Commissioner on the Commissioner's own initiative;

(2) By a petition in the form specified elsewhere in this chapter, e.g., §314.50 for new drug applications, §514.1 for new animal drug applications, or §601.3 for licenses for biologic products; or

(3) By a petition under §10.30.

(b) A notice of opportunity for hearing on a proposal to deny or revoke approval of all or part of an order will be published together with an explanation of the grounds for the proposed action. The notice will describe how to submit requests for hearing. A person subject to the notice has 30 days after its issuance to request a hearing. The 30-day period may not be extended.

(c) The Commissioner may use an optional procedure specified in §10.30(h) to consider issuing, amending, or revoking an order.

(d) In a proceeding under sections 505(e), 512(e) or (m), or 515(e) of the act in which a party wishes to apply for reimbursement of certain expenses under the Equal Access to Justice Act (5 U.S.C. 504 and 504 note), FDA will follow the Department of Health and Human Services' regulations in 45 CFR part 13.

[44 FR 22339, Apr. 13, 1979, as amended at 47 FR 25734, June 15, 1982; 54 FR 9035, Mar. 3, 1989; 85 FR 72906, Nov. 16, 2020]

§ 12.22 Filing objections and requests for a hearing on a regulation or order.

(a) Objections and requests for a hearing under §12.20(d) must be submitted to the Dockets Management Staff and will be accepted for filing if they meet the following conditions:

(1) They are submitted within the time specified in §12.20(e).

(2) Each objection is separately numbered.

(3) Each objection specifies with particularity the provision of the regulation or proposed order objected to.

(4) Each objection on which a hearing is requested specifically so states. Failure to request a hearing on an objection constitutes a waiver of the right to a hearing on that objection.

(5) Each objection for which a hearing is requested includes a detailed de-

scription and analysis of the factual information to be presented in support of the objection. Failure to include a description and analysis for an objection constitutes a waiver of the right to a hearing on that objection. The description and analysis may be used only for the purpose of determining whether a hearing has been justified under §12.24, and do not limit the evidence that may be presented if a hearing is granted.

(i) A copy of any report, article, survey, or other written document relied upon must be submitted, except if the document is—

(a) An FDA document that is routinely publicly available; or

(b) A recognized medical or scientific textbook that is readily available to the agency.

(ii) A summary of the nondocumentary testimony to be presented by any witnesses relied upon must be submitted.

(b) Requests for hearing submitted under §12.21 will be submitted to the Dockets Management Staff and will be accepted for filing if they meet the following conditions:

(1) They are submitted on or before the 30th day after the date of publication of the notice of opportunity for hearing.

(2) They comply with §§314.200, 514.200, or 601.7(a).

(c) If an objection or request for a public hearing fails to meet the requirements of this section and the deficiency becomes known to the Dockets Management Staff, the Dockets Management Staff shall return it with a copy of the applicable regulations, indicating those provisions not complied with. A deficient objection or request for a hearing may be supplemented and subsequently filed if submitted within the 30-day time period specified in §12.20(e) or §12.21(b).

(d) If another person objects to a regulation issued in response to a petition submitted under §12.20(a)(2), the petitioner may submit a written reply to the Dockets Management Staff.

[44 FR 22339, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989; 64 FR 69190, Dec. 10, 1999]