

(2) By a petition—

(i) In the form specified elsewhere in this chapter, e.g., the form for a color additive petition in §71.1 or for an antibiotic petition in §431.50; or

(ii) If no form is specified, by a petition under §10.30.

(b) If the Commissioner receives a petition under paragraph (a)(2) of this section, the Commissioner will—

(1) If it involves any matter subject to section 701(e) of the act or section 4 or 5 of the Fair Packaging and Labeling Act, and meets the requirements for filing, follow the provisions of §10.40 (b) through (f);

(2) If it involves a color additive or food additive, and meets the requirements for filing in §§71.1 and 71.2, or in §§171.1, 171.6, 171.7, and 171.100, publish a notice of filing of the petition within 30 days after the petition is filed instead of a notice of proposed rulemaking.

(c) The Commissioner may issue, amend, or revoke an antibiotic regulation without the requirements of notice and public procedure in §10.40(b) or delayed effective date in §10.40(c)(4), on the Commissioner's own initiative or as a result of a petition containing the required evidence of safety and effectiveness in the circumstances described in §10.40(e)(1).

(d) The notice promulgating the regulation will describe how to submit objections and requests for hearing.

(e) On or before the 30th day after the date of publication of a final regulation, or of a notice withdrawing a proposal initiated by a petition under §10.25(a), a person may submit to the Commissioner written objections and a request for a hearing. The 30-day period may not be extended except that additional information supporting an objection may be received after 30 days upon a showing of inadvertent omission and hardship, and if review of the objection and request for hearing will not thereby be impeded. If, after a final color additive regulation is published, a petition or proposal relating to the regulation is referred to an advisory committee in accordance with section 721(b)(5)(C) of the act, objections and requests for a hearing may be submitted on or before the 30th day after the date on which the order confirming or

modifying the Commissioner's previous order is published.

§12.21 Initiation of a hearing involving the issuance, amendment, or revocation of an order.

(a) A proceeding under section 505 (d) or (e), 512 (d), (e), (m) (3) or (4), of section 515(g)(1) of the act, or section 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, §514.2 for applications for animal feeds, 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]

§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 Branch 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 description 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;

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

(c) A designated journal listed in § 510.95.

(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 Branch 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 Branch, the Dockets Management Branch 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 Branch.

[44 FR 22339, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989]

§ 12.23 Notice of filing of objections.

As soon as practicable after the expiration of the time for filing objections to and requests for hearing on agency action involving the issuance, amendment, or revocation of a regulation under sections 502(n), 701(e), or 721(d) of the act or sections 4 or 5 of the Fair Packaging and Labeling Act, the Commissioner shall publish a notice in the FEDERAL REGISTER specifying those parts of the regulation that have been stayed by the filing of proper objections and, if no objections have been filed, stating that fact. The notice does not constitute a determination that a hearing is justified on any objections or requests for hearing that have been filed. When to do so will cause no undue delay, the notice required by this section may be combined with the notices described in §§ 12.28 and 12.35.

§ 12.24 Ruling on objections and requests for hearing.

(a) As soon as possible the Commissioner will review all objections and requests for hearing filed under § 12.22 and determine—

(1) Whether the regulation should be modified or revoked under § 12.26;

(2) Whether a hearing has been justified; and

(3) Whether, if requested, a hearing before a Public Board of Inquiry under part 13 or before a public advisory committee under part 14 or before the Commissioner under part 15 has been justified.

(b) A request for a hearing will be granted if the material submitted shows the following:

(1) There is a genuine and substantial issue of fact for resolution at a hearing. A hearing will not be granted on issues of policy or law.

(2) The factual issue can be resolved by available and specifically identified