

## § 12.24

## 21 CFR Ch. I (4-1-04 Edition)

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 reliable evidence. A hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions.

(3) The data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the person. A hearing will be denied if the Commissioner concludes that the data and information submitted are insufficient to justify the factual determination urged, even if accurate.

(4) Resolution of the factual issue in the way sought by the person is adequate to justify the action requested. A hearing will not be granted on factual issues that are not determinative with respect to the action requested, e.g., if the Commissioner concludes that the action would be the same even if the factual issue were resolved in the way

sought, or if a request is made that a final regulation include a provision not reasonably encompassed by the proposal. A hearing will be granted upon proper objection and request when a food standard or other regulation is shown to have the effect of excluding or otherwise affecting a product or ingredient.

(5) The action requested is not inconsistent with any provision in the act or any regulation in this chapter particularizing statutory standards. The proper procedure in those circumstances is for the person requesting the hearing to petition for an amendment or waiver of the regulation involved.

(6) The requirements in other applicable regulations, e.g., §§ 10.20, 12.21, 12.22, 314.200, 514.200, and 601.7(a), and in the notice promulgating the final regulation or the notice of opportunity for hearing are met.

(c) In making the determination in paragraph (a) of this section, the Commissioner may use any of the optional procedures specified in § 10.30(h) or in other applicable regulations, e.g., §§ 314.200, 514.200, and 601.7(a).

(d) If it is uncertain whether a hearing has been justified under the principles in paragraph (b) of this section, and the Commissioner concludes that summary decision against the person requesting a hearing should be considered, the Commissioner may serve upon the person by registered mail a proposed order denying a hearing. The person has 30 days after receipt of the proposed order to demonstrate that the submission justifies a hearing.

[44 FR 22339, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989; 64 FR 399, Jan. 5, 1999]

### § 12.26 Modification or revocation of regulation or order.

If the Commissioner determines upon review of an objection or request for hearing that the regulation or order should be modified or revoked, the Commissioner will promptly take such action by notice in the FEDERAL REGISTER. Further objections to or requests for hearing on the modification or revocation may be submitted under §§ 12.20 through 12.22 but no further issue may be taken with other provisions in the regulation or order. Objections and requests for hearing that are

not affected by the modification or revocation will remain on file and be acted upon in due course.

**§ 12.28 Denial of hearing in whole or in part.**

If the Commissioner determines upon review of the objections or requests for hearing that a hearing is not justified, in whole or in part, a notice of the determination will be published.

(a) The notice will state whether the hearing is denied in whole or in part. If the hearing is denied in part, the notice will be combined with the notice of hearing required by § 12.35, and will specify the objections and requests for hearing that have been granted and denied.

(1) Any denial will be explained. A denial based on an analysis of the information submitted to justify a hearing will explain the inadequacy of the information.

(2) The notice will confirm or modify or stay the effective date of the regulation or order involved.

(b) The record of the administrative proceeding relating to denial of a public hearing in whole or in part on an objection or request for hearing consists of the following:

(1) If the proceeding involves a regulation—

(i) The documents specified in § 10.40(g);

(ii) The objections and requests for hearing filed by the Division of Dockets Management;

(iii) If the proceeding involves a color additive regulation referred to an advisory committee in accordance with section 721(b)(5)(C) of the act, the committee's report and the record of the committee's proceeding; and

(iv) The notice denying a formal evidentiary public hearing.

(2) If the proceeding involves an order—

(i) The notice of opportunity for hearing;

(ii) The requests for hearing filed by the Division of Dockets Management;

(iii) The transcripts, minutes of meetings, reports, FEDERAL REGISTER notices, and other documents constituting the record of any of the optional procedures specified in § 12.24(c) used by the Commissioner, but not the tran-

script of a closed portion of a public advisory committee meeting; and

(iv) The notice denying the hearing.

(c) The record specified in paragraph (b) of this section is the exclusive record for the Commissioner's decision on the complete or partial denial of a hearing. The record of the proceeding will be closed as of the date of the Commissioner's decision unless another date is specified. A person who requested and was denied a hearing may submit a petition for reconsideration under § 10.33 or a petition for stay of action under § 10.35. A person who wishes to rely upon information or views not included in the administrative record shall submit them to the Commissioner with a petition under § 10.25(a) to modify the final regulation or order.

(d) Denial of a request for a hearing in whole or in part is final agency action reviewable in the courts, under the statutory provisions governing the matter involved, as of the date of publication of the denial in the FEDERAL REGISTER.

(1) Before requesting a court for a stay of action pending review, a person shall first submit a petition for a stay of action under § 10.35.

(2) Under 28 U.S.C. 2112(a), FDA will request consolidation of all petitions on a particular matter.

(3) The time for filing a petition for judicial review of a denial of a hearing on an objection or issue begins on the date the denial is published in the FEDERAL REGISTER, (i) When an objection or issues relates to a regulation, if a hearing is denied on all objections and issues concerning a part of the proposal the effectiveness of which has not been deferred pending a hearing on other parts of the proposal; or (ii) when an issue relates to an order, if a hearing is denied on all issues relating to a particular new drug application, new animal drug application, device premarket approval application or product development protocol, or biologics license. The failure to file a petition for judicial review within the period established in the statutory provision governing the matter involved constitutes a waiver of the right to judicial review of the objection or issue, regardless