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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 §1502.8, 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, unless the

document is-

(A) A CPSC document that is routinely publicly available; or

- (B) A recognized medical or scientific textbook or journal in the public domain.
- (ii) A summary of the non-documentary testimony to be presented by any witnesses relied upon must be submitted.
- (b) If an objection or request for a public hearing fails to meet the requirements of this section the Office of the General Counsel shall notify the Office of the Secretary of the deficiency. The Office of the Secretary 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 §1502.5(b).
- (c) If another person objects to a regulation issued in response to a petition, the petitioner may submit a written reply to the Office of the Secretary on or before the 15th day after the last day for filing objections.

§ 1502.7 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 the FHSA or the PPPA and section 701(e) of the Federal Food, Drug, and Cosmetic Act, the Commission 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 §§ 1502.10 and 1502.13.

§1502.8 Ruling on objections and requests for hearing.

- (a) As soon as practicable, the Commission will review all objections and requests for hearing filed under §1502.6 and determine—
- (1) Whether the regulation should be modified or revoked under §1502.9; and
- (2) Whether a hearing 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 Commission concludes that the data and information submitted, even though accurate, are insufficient to justify the factual determination urged.
- (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 Commission concludes that the Commission's 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.
- (5) The action requested is not inconsistent with any provision in the FHSA or any regulation in 16 CFR subchapter C explaining or particularizing the requirements of the FHSA.
- (6) The requirements in other applicable regulations, and in the notice promulgating the final regulation or

the notice of opportunity for hearing are met.

- (c) In making the determinations specified in paragraph (a) of this section, the Commission may issue an appropriate order on the determinations without further notice or opportunity for comment from interested parties. However, the Commission, at its option, may use the procedure specified in 16 CFR part 1052 or any other applicable public procedure available to it.
- (d) If it is uncertain whether a hearing has been justified under the principles in paragraph (b) of this section, and the Commission concludes that summary decision against the person requesting a hearing should be considered, the Commission 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.

§ 1502.9 Modification or revocation of regulation or order.

If, upon review of an objection or request for hearing, the Commission determines that the regulation should be modified or revoked, the Commission 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 §§1502.5 and 1502.6, but no further issue may be taken with other provisions in the regulation. 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.

§ 1502.10 Denial of hearing in whole or in part.

- (a) If the Commission 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 in the FEDERAL REGISTER.
- (b) 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 §1502.13, and will specify the objections and requests for hearing that have been granted and denied.

- (c) 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.
- (d) The notice will confirm, modify, or stay the effective date of the regulation involved.
- (e) The record of the administrative proceeding relating to denial in whole or in part of a public hearing on an objection or request for hearing consists of the following:
 - (1) The entire rulemaking record;
- (2) The objections and requests for hearing filed by the Office of the Secretary; and
- (3) The notice denying a formal evidentiary public hearing.
- (f) The record specified in paragraph (e) of this section is the exclusive record for the Commission'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 Commission's decision denying a hearing, unless another date is specified. A person who requested and was denied a hearing may submit a petition for reconsideration or a petition for stay of the Commission's action. A person who wishes to rely upon information or views not included in the administrative record shall submit them to the Commission with a petition to modify the final regulation.
- (g) 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 the Commission's action pending judicial review, a person shall first submit a petition to the Commission for a stay of action.
- (2) 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. 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,