

collaboration of two or more individuals.

(b) Electronic signatures based upon biometrics shall be designed to ensure that they cannot be used by anyone other than their genuine owners.

§ 11.300 Controls for identification codes/passwords.

Persons who use electronic signatures based upon use of identification codes in combination with passwords shall employ controls to ensure their security and integrity. Such controls shall include:

(a) Maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.

(b) Ensuring that identification code and password issuances are periodically checked, recalled, or revised (e.g., to cover such events as password aging).

(c) Following loss management procedures to electronically deauthorize lost, stolen, missing, or otherwise potentially compromised tokens, cards, and other devices that bear or generate identification code or password information, and to issue temporary or permanent replacements using suitable, rigorous controls.

(d) Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management.

(e) Initial and periodic testing of devices, such as tokens or cards, that bear or generate identification code or password information to ensure that they function properly and have not been altered in an unauthorized manner.

PART 12—FORMAL EVIDENTIARY PUBLIC HEARING

Subpart A—General Provisions

- Sec.
12.1 Scope.

Subpart B—Initiation of Proceedings

- 12.20 Initiation of a hearing involving the issuance, amendment, or revocation of a regulation.
12.21 Initiation of a hearing involving the issuance, amendment, or revocation of an order.
12.22 Filing objections and requests for a hearing on a regulation or order.
12.23 Notice of filing of objections.
12.24 Ruling on objections and requests for hearing.
12.26 Modification or revocation of regulation or order.
12.28 Denial of hearing in whole or in part.
12.30 Judicial review after waiver of hearing on a regulation.
12.32 Request for alternative form of hearing.
12.35 Notice of hearing; stay of action.
12.37 Effective date of a regulation.
12.38 Effective date of an order.

Subpart C—Appearance and Participation

- 12.40 Appearance.
12.45 Notice of participation.
12.50 Advice on public participation in hearings.

Subpart D—Presiding Officer

- 12.60 Presiding officer.
12.62 Commencement of functions.
12.70 Authority of presiding officer.
12.75 Disqualification of presiding officer.
12.78 Unavailability of presiding officer.

Subpart E—Hearing Procedures

- 12.80 Filing and service of submissions.
12.82 Petition to participate in forma pauperis.
12.83 Advisory opinions.
12.85 Disclosure of data and information by the participants.
12.87 Purpose; oral and written testimony; burden of proof.
12.89 Participation of nonparties.
12.90 Conduct at oral hearings or conferences.
12.91 Time and place of prehearing conference.
12.92 Prehearing conference procedure.
12.93 Summary decisions.
12.94 Receipt of evidence.
12.95 Official notice.
12.96 Briefs and argument.
12.97 Interlocutory appeal from ruling of presiding officer.
12.98 Official transcript.
12.99 Motions.

Subpart F—Administrative Record

- 12.100 Administrative record of a hearing.
12.105 Examination of record.

§ 12.1

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

Subpart G—Initial and Final Decisions

- 12.120 Initial decision.
- 12.125 Appeal from or review of initial decision.
- 12.130 Decision by Commissioner on appeal or review of initial decision.
- 12.139 Reconsideration and stay of action.

Subpart H—Judicial Review

- 12.140 Review by the courts.
- 12.159 Copies of petitions for judicial review.

AUTHORITY: 21 U.S.C. 141-149, 321-393, 467f, 679, 821, 1034; 42 U.S.C. 201, 262, 263b-263n, 264; 15 U.S.C. 1451-1461; 5 U.S.C. 551-558, 701-721; 28 U.S.C. 2112.

SOURCE: 44 FR 22339, Apr. 13, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 12.1 Scope.

The procedures in this part apply when—

- (a) A person has a right to an opportunity for a hearing under the laws specified in § 10.50; or
- (b) The Commissioner concludes that it is in the public interest to hold a formal evidentiary public hearing on any matter before FDA.

Subpart B—Initiation of Proceedings

§ 12.20 Initiation of a hearing involving the issuance, amendment, or revocation of a regulation.

(a) A proceeding under section 409(f), 502(n), 512(n)(5), 701(e), or 721(d) of the act or section 4 or 5 of the Fair Packaging and Labeling Act may be initiated—

(1) By the Commissioner on the Commissioner's own initiative, e.g., as provided in § 170.15 for food additives; or

(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

(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 Label-

ing 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) [Reserved]

(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.

[44 FR 22339, Apr. 13, 1979, as amended at 64 FR 399, Jan. 5, 1999]

§ 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.