

Food and Drug Administration, HHS

§ 12.20

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.

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. 41–50, 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), 507(f), 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