

PART 12—FORMAL EVIDENTIARY PUBLIC HEARING

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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