

## § 16.119

should be taken and, if so, in what form.

(b) With respect to a regulatory hearing required by the act or a regulation under § 16.1(b)—

(1) The administrative record of the hearing specified in § 16.80(a) constitutes the exclusive record for decision;

(2) On the basis of the administrative record of the hearing, the Commissioner shall issue a written decision stating the reasons for the Commissioner's administrative action and the basis in the record; and

(3) For purposes of judicial review under § 10.45, the record of the administrative proceeding consists of the record of the hearing and the Commissioner's decision.

### Subpart F—Reconsideration and Stay

#### § 16.119 Reconsideration and stay of action.

After any final administrative action that is the subject of a hearing under this part, any party may petition the Commissioner for reconsideration of any part or all of the decision or action under § 10.33 or may petition for a stay of the decision or action under § 10.35.

[44 FR 22367, Apr. 13, 1979, as amended at 54 FR 9037, Mar. 3, 1989]

### Subpart G—Judicial Review

#### § 16.120 Judicial review.

Section 10.45 governs the availability of judicial review concerning any regulatory action which is the subject of a hearing under this part

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AUTHORITY: 21 U.S.C. 331, 333, 337, 351, 352, 355, 360, 360c, 360f, 360i, 360j, 371; 42 U.S.C. 262, 263b, 300aa–28; 5 U.S.C. 554, 555, 556, 557.

SOURCE: 60 FR 38626, July 27, 1995, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 17 appear at 68 FR 24879, May 9, 2003.

#### § 17.1 Scope.

This part sets forth practices and procedures for hearings concerning the administrative imposition of civil money penalties by FDA. Listed below are the statutory provisions that as of August 28, 1995, authorize civil money penalties that are governed by these procedures.

(a) Section 303 (b)(2) through (b)(4) of the Federal Food, Drug, and Cosmetic Act (the act) authorizing civil money penalties for certain violations of the act that relate to prescription drug marketing practices.

(b) Section 303(g) of the act authorizing civil money penalties for certain violations of the act that relate to medical devices.

(c) Section 307 of the act authorizing civil money penalties for certain actions in connection with an abbreviated new drug application or certain actions in connection with a person or individual debarred under section 306 of the act.