the hearing will be given the opportunity to review and comment on the presiding officer's report of the hearing.

(f) The presiding officer shall include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and shall include a recommended decision, with a statement of reasons, unless the Commissioner directs otherwise.

(g) The presiding officer has the power to take such actions and make such rulings as are necessary or appropriate to maintain order and to conduct a fair, expeditious, and impartial hearing, and to enforce the requirements of this part concerning the conduct of hearings. The presiding officer may direct that the hearing be conducted in any suitable manner permitted by law and these regulations.

(h) The Commissioner or the presiding officer has the power under §10.19 to suspend, modify, or waive any provision of this part.

[44 FR 22367, Apr. 13, 1979, as amended at 66 FR 6469, Jan. 22, 2001; 66 FR 12850, Mar. 1, 2001]

EFFECTIVE DATE NOTE: At 66 FR 12850, Mar. 1, 2001, §16.60 was amended by adding paragraph (a)(3), effective Jan. 22, 2001, to Apr. 22, 2001.

§ 16.62 Right to counsel.

Any party to a hearing under this part has the right at all times to be advised and accompanied by counsel.

Subpart E—Administrative Record and Decision

§ 16.80 Administrative record of a regulatory hearing.

(a) The administrative record of the regulatory hearing consists of the following:

(1) The notice of opportunity for hearing and the response.

(2) All written information and views submitted to the presiding officer at the hearing or after if specifically permitted by the presiding officer.

(3) Any transcript of the hearing.

(4) The presiding officer's report of the hearing and comments on the report under §16.60(e).

(5) All letters and memoranda of meetings or communications between participants and the presiding officer or the Commissioner referred to in §16.44(c).

(b) The record of the regulatory hearing is closed to the submission of information and views, at the close of the hearing, unless the presiding officer specifically permits additional time for a further submission.

§ 16.85 Examination of administrative record.

Part 20 governs the availability for public disclosure of each document that is a part of the administrative record of a regulatory hearing.

§ 16.95 Administrative decision and record for decision.

(a) With respect to a regulatory hearing at the Commissioner's initiative under §16.1(a), the Commissioner shall consider the administrative record of the hearing specified in §16.80(a) together with all other relevant information and views available to FDA in determining whether regulatory action 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

PART 17—CIVIL MONEY PENALTIES HEARINGS

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.

§ 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.

(d) Section 351(d)(2)(B) of the Public Health Service Act (the PHS Act) authorizing civil money penalties for violations of biologic recall orders.

(e) Section 354(h)(2) of the PHS Act, as amended by the Mammography Quality Standards Act of 1992, authorizing civil money penalties for failure to obtain a certificate, failure to comply with established standards, among other things.

(f) Section 2128 of the PHS Act authorizing civil money penalties for intentionally destroying, altering, falsifying, or concealing any record or report required to be prepared, maintained, or submitted by vaccine manufacturers pursuant to that section of the PHS Act.

§ 17.3 Definitions.

The following definitions are applicable in this part:

(a) For specific acts giving rise to civil money penalty actions brought under 21 U.S.C. 333(g)(1):

(1) *Significant departure*, for the purpose of interpreting 21 U.S.C. 333(g)(1)(B)(i), means a departure from requirements that is either a single major incident or a series of incidents that collectively are consequential.