

**§ 17.9 Answer.**

(a) The respondent may request a hearing by filing an answer with the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, within 30 days of service of the complaint. Unless stated otherwise, an answer shall be deemed to be a request for hearing.

(b) In the answer, the respondent:

(1) Shall admit or deny each of the allegations of liability made in the complaint; allegations not specifically denied in an answer are deemed admitted;

(2) Shall state all defenses on which the respondent intends to rely;

(3) Shall state all reasons why the respondent contends that the penalties and assessments should be less than the requested amount; and

(4) Shall state the name, address, and telephone number of the respondent's counsel, if any.

(c) If the respondent is unable to file an answer meeting the requirements of paragraph (b) of this section within the time provided, the respondent shall, before the expiration of 30 days from service of the complaint, file a request for an extension of time within which to file an answer that meets the requirements of paragraph (b) of this section. The presiding officer may, for good cause shown, grant the respondent up to 30 additional days within which to file an answer that meets the requirements of paragraph (b) of this section.

(d) The respondent may, on motion, amend its answer to conform with the evidence as justice may require.

**§ 17.11 Default upon failure to file an answer.**

(a) If the respondent does not file an answer within the time prescribed in § 17.9 and if service has been effected as provided in § 17.7, the presiding officer shall assume the facts alleged in the complaint to be true, and, if such facts establish liability under the relevant statute, the presiding officer shall issue an initial decision within 30 days of the time the answer was due, imposing:

(1) The maximum amount of penalties provided for by law for the violations alleged; or

(2) The amount asked for in the complaint, whichever amount is smaller.

(b) Except as otherwise provided in this section, by failing to file a timely answer, the respondent waives any right to a hearing and to contest the amount of the penalties and assessments imposed under paragraph (a) of this section, and the initial decision shall become final and binding upon the parties 30 days after it is issued.

(c) If, before such a decision becomes final, the respondent files a motion seeking to reopen on the grounds that extraordinary circumstances prevented the respondent from filing an answer, the initial decision shall be stayed pending a decision on the motion.

(d) If, on such motion, the respondent can demonstrate extraordinary circumstances excusing the failure to file an answer in a timely manner, the presiding officer may withdraw the decision under paragraph (a) of this section, if such a decision has been issued, and shall grant the respondent an opportunity to answer the complaint as provided in § 17.9(a).

(e) If the presiding officer decides that the respondent's failure to file an answer in a timely manner is not excused, he or she shall affirm the decision under paragraph (a) of this section, and the decision shall become final and binding upon the parties 30 days after the presiding officer issues the decision on the respondent's motion filed under paragraph (c) of this section.

**§ 17.13 Notice of hearing.**

After an answer has been filed, the Center shall serve a notice of hearing on the respondent. Such notice shall include:

(a) The date, time, and place of a prehearing conference, if any, or the date, time, and place of the hearing if there is not to be a prehearing conference;

(b) The nature of the hearing and the legal authority and jurisdiction under which the hearing is to be held;

(c) A description of the procedures for the conduct of the hearing;

(d) The names, addresses, and telephone numbers of the representatives

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of the government and of the respondent, if any; and

(e) Such other matters as the Center or the presiding officer deems appropriate.

### § 17.15 Parties to the hearing.

(a) The parties to the hearing shall be the respondent and the Center(s) with jurisdiction over the matter at issue. No other person may participate.

(b) The parties may at any time prior to a final decision by the entity deciding any appeal agree to a settlement of all or a part of the matter. The settlement agreement shall be filed in the docket and shall constitute complete or partial resolution of the administrative case as so designated by the settlement agreement. The settlement document shall be effective upon filing in the docket and need not be ratified by the presiding officer or the Commissioner of Food and Drugs.

(c) The parties may be represented by counsel, who may be present at the hearing.

### § 17.17 Summary decisions.

(a) At any time after the filing of a complaint, a party may move, with or without supporting affidavits (which, for purposes of this part, shall include declarations under penalty of perjury), for a summary decision on any issue in the hearing. The other party may, within 30 days after service of the motion, which may be extended for an additional 10 days for good cause, serve opposing affidavits or countermove for summary decision.

The presiding officer may set the matter for argument and call for the submission of briefs.

(b) The presiding officer shall grant the motion if the pleadings, affidavits, and other material filed in the record, or matters officially noticed, show that there is no genuine issue as to any material fact and that the party is entitled to summary decision as a matter of law.

(c) Affidavits shall set forth only such facts as would be admissible in evidence and shall show affirmatively that the affiant is competent to testify to the matters stated. When a motion for summary decision is made and supported as provided in this regulation, a

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party opposing the motion may not rest on mere allegations or denials or general descriptions of positions and contentions; affidavits or other responses must set forth specific facts showing that there is a genuine issue of material fact for the hearing.

(d) If, on motion under this section, a summary decision is not rendered on all issues or for all the relief asked, and if additional facts need to be developed, the presiding officer will issue an order specifying the facts that appear without substantial controversy and directing further evidentiary proceedings on facts still at issue. The facts specified not to be at issue shall be deemed established.

(e) Except as provided in § 17.18, a party may not obtain interlocutory review by the entity deciding the appeal (currently the DAB) of a partial summary decision of the presiding officer. A review of final summary decisions on all issues may be had through the procedure set forth in § 17.47.

### § 17.18 Interlocutory appeal from ruling of presiding officer.

(a) Except as provided in paragraph (b) of this section, rulings of the presiding officer may not be appealed before consideration on appeal of the entire record of the hearing.

(b) A ruling of the presiding officer is subject to interlocutory appeal to the entity deciding the appeal (currently the DAB) if the presiding officer certifies on the record or in writing that immediate review is necessary to prevent exceptional delay, expense, or prejudice to any participant, or substantial harm to the public interest.

(c) When an interlocutory appeal is made, a participant may file a brief on the appeal only if specifically authorized by the presiding officer or the entity deciding the appeal (currently the DAB), and if such authorization is granted, only within the period allowed by the presiding officer or the entity deciding the appeal. If a participant is authorized to file a brief, any other participant may file a brief in opposition, within the period allowed by the entity deciding the appeal (currently the DAB). The deadline for filing an interlocutory appeal is subject to the discretion of the presiding officer.