

§ 17.33 The hearing and burden of proof.

(a) The presiding officer shall conduct a hearing on the record to determine whether the respondent is liable for a civil money penalty and, if so, the appropriate amount of any such civil money penalty considering any aggravating or mitigating factors.

(b) In order to prevail, the Center must prove respondent's liability and the appropriateness of the penalty under the applicable statute by a preponderance of the evidence.

(c) The respondent must prove any affirmative defenses and any mitigating factors by a preponderance of the evidence.

(d) The hearing shall be open to the public unless otherwise ordered by the presiding officer, who may order closure only to protect trade secrets or confidential commercial information, as defined in § 20.61 of this chapter, information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, or other information that would be withheld from public disclosure under part 20 of this chapter.

§ 17.34 Determining the amount of penalties and assessments.

(a) When determining an appropriate amount of civil money penalties and assessments, the presiding officer and the Commissioner of Food and Drugs or entity designated by the Commissioner to decide the appeal (currently the DAB) shall evaluate any circumstances that mitigate or aggravate the violation and shall articulate in their opinions the reasons that support the penalties and assessments imposed.

(b) The presiding officer and the entity deciding the appeal shall refer to the factors identified in the statute under which the penalty is assessed for purposes of determining the amount of penalty.

(c) Nothing in this section shall be construed to limit the presiding officer or the entity deciding the appeal from considering any other factors that in any given case may mitigate or aggravate the offense for which penalties and assessments are imposed.

§ 17.35 Sanctions.

(a) The presiding officer may sanction a person, including any party or counsel for:

(1) Failing to comply with an order, subpoena, rule, or procedure governing the proceeding;

(2) Failing to prosecute or defend an action; or

(3) Engaging in other misconduct that interferes with the speedy, orderly, or fair conduct of the hearing.

(b) Any such sanction, including, but not limited to, those listed in paragraphs (c), (d), and (e) of this section, shall reasonably relate to the severity and nature of the failure or misconduct.

(c) When a party fails to comply with a discovery order, including discovery and subpoena provisions of this part, the presiding officer may:

(1) Draw an inference in favor of the requesting party with regard to the information sought;

(2) Prohibit the party failing to comply with such order from introducing evidence concerning, or otherwise relying upon, testimony relating to the information sought; and

(3) Strike any part of the pleadings or other submissions of the party failing to comply with such request.

(d) The presiding officer may exclude from participation in the hearing any legal counsel, party, or witness who refuses to obey an order of the presiding officer. In the case of repeated refusal, the presiding officer may grant judgment to the opposing party.

(e) If a party fails to prosecute or defend an action under this part after service of a notice of hearing, the presiding officer may dismiss the action or may issue an initial decision imposing penalties and assessments.

(f) The presiding officer may refuse to consider any motion, request, response, brief, or other document that is not filed in a timely fashion or in compliance with the rules of this part.

(g) Sanctions imposed under this section may be the subject of an interlocutory appeal as allowed in § 17.18(b), provided that no such appeal will stay or delay a proceeding.