

§ 17.43

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designated by the Commissioner of Food and Drugs to decide the appeal, currently the DAB.

(c) The administrative record may be inspected and copied (upon payment of a reasonable fee) by anyone unless otherwise ordered by the presiding officer, who shall upon motion of any party order otherwise when necessary 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.

§ 17.43 Posthearing briefs.

Any party may file a posthearing brief. The presiding officer shall fix the time for filing such briefs (which shall be filed simultaneously), which shall not exceed 60 days from the date the parties received the transcript of the hearing or, if applicable, the stipulated record. Such briefs may be accompanied by proposed findings of fact and conclusions of law. The presiding officer may permit the parties to file responsive briefs. No brief may exceed 30 pages (exclusive of proposed findings and conclusions) unless the presiding officer has previously found that the issues in the proceeding are so complex, or the administrative record is so voluminous, as to justify longer briefs, in which case the presiding officer may set a longer page limit. Proposed findings of fact and conclusions of law shall not exceed 30 pages unless the presiding officer has previously found that the issues in the proceeding are so complex, or the administrative record is so voluminous, as to justify longer proposed findings and conclusions, in which case the presiding officer may set a longer page limit.

§ 17.45 Initial decision.

(a) The presiding officer shall issue an initial decision based only on the administrative record. The decision shall contain findings of fact, conclusions of law, and the amount of any penalties and assessments imposed.

(b) The findings of fact shall include a finding on each of the following issues:

(1) Whether the allegations in the complaint are true, and, if so, whether respondent's actions identified in the complaint violated the law;

(2) Whether any affirmative defenses are meritorious; and

(3) If the respondent is liable for penalties or assessments, the appropriate amount of any such penalties or assessments, considering any mitigating or aggravating factors that he or she finds in the case.

(c) The presiding officer shall serve the initial decision or the decision granting summary decision on all parties within 90 days after the time for submission of posthearing briefs and responsive briefs (if permitted) has expired. If the presiding officer believes that he or she cannot meet the 90-day deadline, he or she shall notify the Commissioner of Food and Drugs or other entity designated by the Commissioner to decide the appeal of the reason(s) therefor, and the Commissioner or that entity may then set a new deadline.

(d) Unless the initial decision or the decision granting summary decision of the presiding officer is timely appealed, the initial decision or the decision granting summary decision shall constitute the final decision of FDA and shall be final and binding on the parties 30 days after it is issued by the presiding officer.

§ 17.47 Appeals.

(a) Either the Center or any respondent may appeal an initial decision, including a decision not to withdraw a default judgment, or a decision granting summary decision to the Commissioner of Food and Drugs or other entity the Commissioner designates to decide the appeal. The Commissioner has currently designated the Departmental Appeals Board (DAB) to decide appeals under this part. Parties may appeal to the DAB by filing a notice of appeal with the DAB, rm. 637-D, Hubert H. Humphrey Bldg., 200 Independence Ave. SW., Washington, DC 20201, and the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, in accordance with this section.