

for a hearing under this section and is part of the administrative record of the regulatory hearing under §16.80(a) of this chapter.

(2) A request for a hearing under this subpart must be addressed to the FDA Division Director (or, in the case of a foreign facility, the Director of the Division of Compliance in the Center for Veterinary Medicine) as provided in the order withdrawing an exemption.

(3) Section 507.75, rather than §16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart.

(4) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must 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 must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2 calendar days of issuance of the report. The presiding officer will then issue the final decision.

(5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under paragraph (c)(4) of this section are part of the administrative record.

(6) No party shall have the right, under §16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final decision.

(7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing under a regulation in accordance with part 16 of this chapter, except that §16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§16.80(a)(1) through (3), and (a)(5), of this chapter,

and 507.73(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under §10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

[80 FR 56337, Sept. 17, 2015, as amended at 85 FR 16554, Mar. 24, 2020]

**§ 507.75 Presiding officer for an appeal and for an informal hearing.**

The presiding officer for an appeal, and for an informal hearing, must be an Office of Regulatory Affairs Program Director or another FDA official senior to an FDA Division Director.

[85 FR 16555, Mar. 24, 2020]

**§ 507.77 Timeframe for issuing a decision on an appeal.**

(a) If you appeal the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the 10th calendar day after the appeal is filed.

(b) If you appeal the order and request an informal hearing:

(1) If FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under §507.73(c)(4), and must issue a final decision within 10 calendar days after the hearing is held; or

(2) If FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed.

**§ 507.80 Revocation of an order to withdraw a qualified facility exemption.**

An order to withdraw a qualified facility exemption is revoked if:

(a) You appeal the order and request an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time; or