

**§ 1.691 How do I request reconsideration of a denial by FDA of an application or a waiver request?**

(a) An accreditation body may seek reconsideration of the denial of an application for recognition, renewal of recognition, or reinstatement of recognition no later than 10 business days after the date of the issuance of such denial.

(b) A third-party certification body may seek reconsideration of the denial of an application for direct accreditation, renewal of direct accreditation, reaccreditation of directly accredited third-party certification body, a request for a waiver of the conflict of interest requirement in § 1.650(b), or a waiver extension no later than 10 business days after the date of the issuance of such denial.

(c) A request to reconsider an application or waiver request under paragraph (a) or (b) of this section must be signed by the requestor or by an individual authorized to act on its behalf in submitting the request for reconsideration. The request must be submitted electronically in English and must comply with the procedures described in the notice.

(d) After completing its review and evaluation of the request for reconsideration, FDA will notify the requestor through the issuance of the recognition, direct accreditation, or waiver upon reconsideration or through the issuance of a denial of the application or waiver request under paragraph (a) or (b) of this section upon reconsideration.

**§ 1.692 How do I request internal agency review of a denial of an application or waiver request upon reconsideration?**

(a) No later than 10 business days after the date of issuance of a denial of an application or waiver request upon reconsideration under § 1.691, the requestor may seek internal agency review of such denial under § 10.75(c)(1) of this chapter.

(b) The request for internal agency review under paragraph (a) of this section must be signed by the requestor or by an individual authorized to act on its behalf in submitting the request for internal review. The request must be

submitted electronically in English to the address specified in the denial upon reconsideration and must comply with procedures it describes.

(c) Under § 10.75(d) of this chapter, internal agency review of such denial must be based on the information in the administrative file, which will include any supporting information submitted under § 1.691(c).

(d) After completing the review and evaluation of the administrative file, FDA will notify the requestor of its decision to overturn the denial and grant the application or waiver request through issuance of an application or waiver request upon reconsideration or to affirm the denial of the application or waiver request upon reconsideration through issuance of a denial of an application or waiver request upon reconsideration.

(e) Issuance by FDA of a denial of an application or waiver request upon reconsideration constitutes final agency action under 5 U.S.C. 702.

**§ 1.693 How do I request a regulatory hearing on a revocation of recognition or withdrawal of accreditation?**

(a) *Request for hearing on revocation.* No later than 10 business days after the date of issuance of a revocation of recognition of an accreditation body under § 1.634, an individual authorized to act on the accreditation body's behalf may submit a request for a regulatory hearing on the revocation under part 16 of this chapter. The issuance of revocation issued under § 1.634 will contain all of the elements required by § 16.22 of this chapter and will thereby constitute the notice of an opportunity for hearing under part 16 of this chapter.

(b) *Request for hearing on withdrawal.* No later than 10 business days after the date of issuance of a withdrawal of accreditation of a third-party certification body under § 1.664, an individual authorized to act on the third-party certification body's behalf may submit a request for a regulatory hearing on the withdrawal under part 16 of this chapter. The issuance of withdrawal under § 1.664 will contain all of the elements required by § 16.22 of this chapter and will thereby constitute the notice

of opportunity of hearing under part 16 of this chapter.

(c) *Submission of request for regulatory hearing.* The request for a regulatory hearing under paragraph (a) or (b) of this section must be submitted with a written appeal that responds to the basis for the FDA decision, as described in the issuance of revocation or withdrawal, as appropriate, and includes any supporting information upon which the requestor is relying. The request, appeal, and supporting information must be submitted in English to the address specified in the notice and must comply with the procedures it describes.

(d) *Effect of submission of request on FDA decision.* The submission of a request for a regulatory hearing under paragraph (a) or (b) of this section will not operate to delay or stay the effect of a decision by FDA to revoke recognition of an accreditation body or to withdraw accreditation of a third-party certification body unless FDA determines that a delay or a stay is in the public interest.

(e) *Presiding officer.* The presiding officer for a regulatory hearing for a revocation or withdrawal under this subpart will be designated after a request for a regulatory hearing is submitted to FDA.

(f) *Denial of a request for regulatory hearing.* The presiding officer may deny a request for regulatory hearing for a revocation or withdrawal under § 16.26(a) of this chapter when no genuine or substantial issue of fact has been raised.

(g) *Conduct of regulatory hearing.* (1) If the presiding officer grants a request for a regulatory hearing for a revocation or withdrawal, the hearing will be held within 10 business days after the date the request was filed or, if applicable, within a timeframe agreed upon in writing by requestor, the presiding officer, and FDA.

(2) The presiding officer must conduct the regulatory hearing for revocation or withdrawal under part 16 of this chapter, except that, under § 16.5(b) of this chapter, such procedures apply only to the extent that the procedures are supplementary and do not conflict with the procedures specified for regulatory hearings under this subpart. Ac-

ordingly, the following requirements of part 16 are inapplicable to regulatory hearings under this subpart: § 16.22 (Initiation of a regulatory hearing); § 16.24(e) (timing) and (f) (contents of notice); § 16.40 (Commissioner); § 16.60(a) (public process); § 16.95(b) (administrative decision and record for decision); and § 16.119 (Reconsideration and stay of action).

(3) A decision by the presiding officer to affirm the revocation of recognition or the withdrawal of accreditation is considered a final agency action under 5 U.S.C. 702.

**§ 1.694 Are electronic records created under this subpart subject to the electronic records requirements of part 11 of this chapter?**

Records that are established or maintained to satisfy the requirements of this subpart and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

**§ 1.695 Are the records obtained by FDA under this subpart subject to public disclosure?**

Records obtained by FDA under this subpart are subject to the disclosure requirements under part 20 of this chapter.

REQUIREMENTS FOR USER FEES UNDER THIS SUBPART

SOURCE: Sections 1.700 through 1.725 appear at 81 FR 90193, Dec. 14, 2016, unless otherwise noted.

**§ 1.700 Who is subject to a user fee under this subpart?**

(a) Accreditation bodies submitting applications or renewal applications for recognition in the third-party certification program;

(b) Recognized accreditation bodies participating in the third-party certification program;

(c) Third-party certification bodies submitting applications or renewal applications for direct accreditation; and