

§ 1.691

of such recognized accreditation bodies. FDA will also place on its Web site a list of accreditation bodies for which it has denied renewal of recognition, for which FDA has revoked recognition, and that have relinquished their recognition or have allowed their recognition to expire. FDA will also place in its Web site a list of certification bodies whose renewal of accreditation has been denied, for which FDA has withdrawn accreditation, and that have relinquished their accreditations or have allowed their accreditations to expire. FDA will place on its Web site determinations under § 1.670(a)(1) and modifications of such determinations under § 1.670(a)(2).

§ 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)

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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