

§ 1.670

FDA through direct accreditation no later than 1 year after withdrawal of accreditation, or the original date of the expiration of accreditation, whichever comes first; or

(ii) Under such conditions as FDA may impose in withdrawing accreditation.

(b) *Application following voluntary relinquishment.* A third-party certification body that previously relinquished its accreditation under § 1.665 may seek accreditation by submitting a new application for accreditation under § 1.660 or, where applicable, § 1.670.

ADDITIONAL PROCEDURES FOR DIRECT ACCREDITATION OF THIRD-PARTY CERTIFICATION BODIES UNDER THIS SUBPART

§ 1.670 How do I apply to FDA for direct accreditation or renewal of direct accreditation?

(a) *Eligibility.* (1) FDA will accept applications from third-party certification bodies for direct accreditation or renewal of direct accreditation only if FDA determines that it has not identified and recognized an accreditation body to meet the requirements of section 808 of the FD&C Act within 2 years after establishing the accredited third-party audits and certification program. Such FDA determination may apply, as appropriate, to specific types of third-party certification bodies, types of expertise, or geographic location; or through identification by FDA of any requirements of section 808 of the FD&C Act not otherwise met by previously recognized accreditation bodies. FDA will only accept applications for direct accreditation and renewal applications that are within the scope of the determination.

(2) FDA may revoke or modify a determination under paragraph (a)(1) of this section if FDA subsequently identifies and recognizes an accreditation body that affects such determination.

(3) FDA will provide notice on the Web site described in § 1.690 of a determination under paragraph (a)(1) of this section and of a revocation or modification of the determination under paragraph (a)(1) of this section, as described in paragraph (a)(2) of this section.

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(b) *Application for direct accreditation or renewal of direct accreditation.* (1) A third-party certification body seeking direct accreditation or renewal of direct accreditation must submit an application to FDA, demonstrating that it is within the scope of the determination issued under paragraph (a)(1) of this section, and it meets the eligibility requirements of § 1.640.

(2) Applications and all documents provided as part of the application process must be submitted electronically, in English. An applicant must provide such translation and interpretation services as are needed by FDA to process the application, including during an onsite audit of the applicant.

(3) The application must be signed in the manner designated by FDA by an individual authorized to act on behalf of the applicant for purposes of seeking or renewing direct accreditation.

§ 1.671 How will FDA review my application for direct accreditation or renewal of direct accreditation and what happens once FDA decides on my application?

(a) *Review of a direct accreditation or renewal application.* FDA will examine a third-party certification body's direct accreditation or renewal application for completeness and notify the applicant of any deficiencies. FDA will review applications for direct accreditation and for renewal of direct accreditation on a first in, first out basis according to the date the completed submission is received; however, FDA may prioritize the review of specific applications to meet the needs of the program.

(b) *Evaluation of a direct accreditation or renewal application.* FDA will evaluate any completed application to determine whether the applicant meets the requirements for direct accreditation under this subpart. If FDA does not reach a final decision on a renewal application before the expiration of the direct accreditation, FDA may extend the duration of such direct accreditation for a specified period of time or until the Agency reaches a final decision on the renewal application.

(c) *Notice of approval or denial.* FDA will notify the applicant that its direct accreditation or renewal application