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.

(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

has been approved through issuance of or denied.

(d) *Issuance of direct accreditation.* If an application has been approved, the issuance of the direct accreditation that will list any limitations associated with the accreditation.

(e) *Issuance of denial of direct accreditation.* If FDA issues a denial of direct accreditation or denial of a renewal application, the issuance of the denial of direct accreditation will state the basis for such denial and provide the procedures for requesting reconsideration of the application under § 1.691.

(f) *Notice of records custodian after denial of application for renewal of direct accreditation.* An applicant whose renewal application was denied must notify FDA electronically, in English, within 10 business days of the date of issuance of a denial of a renewal application, of the name and contact information of the custodian who will maintain the records required by § 1.658(a) and make them available to FDA as required by § 1.658(b) and (c). The contact information for the custodian must include, at a minimum, an email address and the physical address where the records required by § 1.658(b) will be located.

(g) *Effect of denial of renewal of direct accreditation on food or facility certifications issued to eligible entities.* A food or facility certification issued by an accredited third-party certification body prior to issuance of the denial of its renewal application will remain in effect until the certification expires. If FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in VQIP.

(h) *Public notice of denial of renewal of direct accreditation.* FDA will provide notice on the Web site described in § 1.690 of the issuance of a denial of renewal application for direct accreditation under this subpart.

§ 1.672 What is the duration of direct accreditation?

FDA will grant direct accreditation of a third-party certification body for a period not to exceed 4 years.

Requirements for Eligible Entities Under This Subpart

§ 1.680 How and when will FDA monitor eligible entities?

FDA may, at any time, conduct an onsite audit of an eligible entity that has received food or facility certification from an accredited third-party certification body under this subpart. Where FDA determines necessary or appropriate, the unannounced audit may be conducted with or without the accredited third-party certification body or the recognized accreditation body (where applicable) present. An FDA audit conducted under this section will be conducted on an unannounced basis and may be preceded by a request for a 30-day operating schedule.

§ 1.681 How frequently must eligible entities be recertified?

An eligible entity seeking recertification of a food or facility certification under this subpart must apply for recertification prior to the expiration of its certification. For certifications used in meeting the requirements of section 801(q) or 806 of the FD&C Act, FDA may require an eligible entity to apply for recertification at any time FDA determines appropriate under such section.

General Requirements of This Subpart

§ 1.690 How will FDA make information about recognized accreditation bodies and accredited third-party certification bodies available to the public?

FDA will place on its Web site a registry of recognized accreditation bodies and accredited third-party certification bodies, including the name, contact information, and scope and duration of recognition or accreditation. The registry may provide information on third-party certification bodies accredited by recognized accreditation bodies through links to the Web sites