the custodian must include, at a minimum, an email address and the physical address where the records required by §1.625(a) will be located.

(f) *Effect of denial of an application for renewal of recognition of an accreditation body on accredited third-party certification bodies.* (1) FDA will issue a notice of the denial of a recognition renewal to any third-party certification bodies accredited by the accreditation body whose renewal application was denied. The third-party certification body's accreditation will remain in effect so long as the third-party certification body:

(i) No later than 60 days after FDA's issuance of the notice of the denial of recognition renewal, conducts a self-assessment under §1.655 and reports the results of the self-assessment to FDA under §1.656(b); and

(ii) No later than 1 year after issuance of the notice of denial of recognition renewal or the original date of the expiration of the accreditation, whichever comes first, becomes accredited by another recognized accreditation body or by FDA through direct accreditation.

(2) FDA may withdraw the accreditation of a third-party certification body whenever FDA determines there is good cause for withdrawal of accreditation under §1.664(c).

(g) *Effect of denial of an application for renewal of recognition of an accreditation body on food or facility certifications issued to eligible entities.* A food or facility certification issued by a third-party certification body accredited by a recognized accreditation body prior to issuance of a denial of the 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 the voluntary qualified importer program (VQIP).

(h) *Public notice of denial of an application for renewal of recognition of an accreditation body.* FDA will provide notice on the Web site described in §1.690 of the date of issuance of a denial of a renewal application and will describe the basis for the denial.

§ 1.632 What is the duration of recognition?

FDA may grant recognition of an accreditation body for a period not to exceed 5 years from the date of recognition.

§ 1.633 How will FDA monitor recognized accreditation bodies?

(a) FDA will evaluate the performance of each recognized accreditation body to determine its compliance with the applicable requirements of this subpart. Such assessment must occur by at least 4 years after the date of recognition for a 5-year recognition period, or by no later than the mid-term point for a recognition period of less than 5 years. FDA may conduct additional assessments of a recognized accreditation body at any time.

(b) An FDA assessment of a recognized accreditation body may include onsite assessments of a representative sample of third-party certification bodies the recognized accreditation body accredited and onsite audits of a representative sample of eligible entities certified by such third-party certification bodies under this subpart. These may be conducted at any time and, as FDA determines necessary or appropriate, may occur without the recognized accreditation body or, in the case of an audit of an eligible entity, the accredited third-party certification body present.

§ 1.634 When will FDA revoke recognition?

(a) *Grounds for revocation of recognition.* FDA will revoke the recognition of an accreditation body found not to be in compliance with the requirements of this subpart, including for any one or more of the following:

(1) Refusal by the accreditation body to allow FDA to access records required by §1.625, or to conduct an assessment or investigation of the accreditation body or of a third-party certification body it accredited to ensure the accreditation body's continued compliance with the requirements of this subpart.

(2) Failure to take timely and necessary corrective action when:

(i) The accreditation of a third-party certification body it accredited is withdrawn by FDA under §1.664(a);

(ii) A significant deficiency is identified through self-assessment under §1.622, monitoring under §1.621, or self-assessment by one or more of its accredited third-party certification bodies under §1.655; or

(iii) Directed to do so by FDA to ensure compliance with this subpart.

(3) A determination by FDA that the accreditation body has committed fraud or has submitted material false statements to the Agency.

(4) A determination by FDA that there is otherwise good cause for revocation, including:

(i) Demonstrated bias or lack of objectivity when conducting activities under this subpart; or

(ii) Failure to adequately support one or more decisions to grant accreditation under this subpart.

(iii) Failure to pay the annual user fee within 90 days of the payment due date, as specified in §1.725(b)(3).

(b) *Records request associated with revocation.* To assist in determining whether revocation is warranted under paragraph (a) of this section, FDA may request records of the accreditation body required by §1.625 or the records, required by §1.658, of one or more of the third-party certification bodies it accredited under this subpart.

(c) *Issuance of revocation of recognition.* (1) FDA will notify an accreditation body that its recognition has been revoked through issuance of a revocation that will state the grounds for revocation, the procedures for requesting a regulatory hearing under §1.693 on the revocation, and the procedures for requesting reinstatement of recognition under §1.636.

(2) Within 10 business days of the date of issuance of the revocation, the accreditation body must notify FDA electronically, in English, of the name of the custodian who will maintain the records and make them available to FDA as required by §1.625. The contact information for the custodian must provide, at a minimum, an email address and the physical address where the records will be located.

(d) *Effect of revocation of recognition of an accreditation body on accredited third-party certification bodies.* (1) FDA will issue a notice of the revocation of recognition to any accredited third-party certification body accredited by the accreditation body whose recognition was revoked. The third-party certification body's accreditation will remain in effect if the third-party certification body:

(i) No later than 60 days after FDA's issuance of the notice of revocation, conducts a self-assessment under §1.655 and reports the results of the self-assessment to FDA under §1.656(b); and

(ii) No later than 1 year after issuance of the notice of the revocation, or the original date of expiration of the accreditation, whichever comes first, becomes accredited by another recognized accreditation body or by FDA through direct accreditation.

(2) FDA may withdraw the accreditation of a third-party certification body whenever FDA determines there is good cause for withdrawal of accreditation under §1.664(c).

(e) *Effect of revocation of recognition of an accreditation body on food or facility certifications issued to eligible entities.* A food or facility certification issued by a third-party certification body accredited by a recognized accreditation body prior to issuance of the revocation of recognition will remain in effect until the certificate terminates by expiration. 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.

(f) *Public notice of revocation of recognition.* FDA will provide notice on the Web site described in §1.690 of the issuance of the revocation of recognition of an accreditation body and will describe the basis for revocation.

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