

## § 1.700

### 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

(d) Accredited third-party certification bodies (whether accredited by recognized accreditation bodies or by FDA through direct accreditation) participating in the third-party certification program.

#### **§ 1.705 What user fees are established under this subpart?**

(a) The following application fees:

(1) Accreditation bodies applying for recognition are subject to an application fee for the estimated average cost of the work FDA performs in reviewing and evaluating applications for recognition of accreditation bodies.

(2) Recognized accreditation bodies submitting renewal applications are subject to a renewal application fee for the estimated average cost of the work FDA performs in reviewing and evaluating renewal applications for recognition of accreditation bodies.

(3) Third-party certification bodies applying for direct accreditation are subject to an application fee for the estimated average cost of the work FDA performs in reviewing and evaluating applications for direct accreditation.

(4) Accredited third-party certification bodies applying for renewal of direct accreditation are subject to an application fee for the estimated average cost of the work FDA performs in reviewing and evaluating renewal applications for direct accreditation.

(b) The following annual fees:

(1) Recognized accreditation bodies are subject to an annual fee for the estimated average cost of the work FDA performs to monitor performance of

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recognized accreditation bodies under § 1.633.

(2) Third-party certification bodies directly accredited by FDA are subject to an annual fee for the estimated average cost of the work FDA performs to monitor directly accredited third-party certification bodies under § 1.662.

(3) Third-party certification bodies accredited by recognized accreditation bodies are subject to an annual fee for the estimated average cost of the work FDA performs to monitor third-party certification bodies that are accredited by a recognized accreditation body under § 1.662.

#### **§ 1.710 How will FDA notify the public about the fee schedule?**

FDA will notify the public of the fee schedule annually. The fee notice will be made publicly available prior to the beginning of the fiscal year for which the fees apply, except for the first fiscal year in which this regulation is effective. Each new fee schedule will be adjusted for inflation and improvements in the estimates of the cost to FDA of performing relevant work for the upcoming year.

#### **§ 1.715 When must a user fee required by this subpart be submitted?**

(a) Accreditation bodies applying for recognition and third-party certification bodies applying for direct accreditation must submit a fee concurrently with submitting an application or a renewal application.

(b) Accreditation bodies and third-party certification bodies subject to an annual fee must submit payment within 30 days of receiving billing for the fee.

#### **§ 1.720 Are user fees under this subpart refundable?**

User fees accompanying completed applications and annual fees under this subpart are not refundable.

#### **§ 1.725 What are the consequences of not paying a user fee under this subpart on time?**

(a) An application for recognition or renewal of recognition will not be considered complete for the purposes of