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ALERTS

Food, Drug & Device Law Alert - FDA Issues Proposed Rule And Draft Guidance On User Fee Program For Accreditation Of Third-Party Auditors/Certification Bodies To Conduct Food Safety Audits And To Issue Certifications

July 27, 2015 | Atlanta | Chicago | Columbus | Dallas | Delaware | Elkhart | Fort Wayne | Grand Rapids | Indianapolis | Los Angeles | Minneapolis | South Bend

The FDA recently issued a proposed rule and a draft guidance to establish a user fee program to pay for the accreditation of third-party auditors and certification bodies to conduct food safety audits and to issue certifications. Under the proposed rule FDA will recognize accreditation bodies (ABs) that will in turn certify third-party auditors and certification bodies (CBs) to audit and certify registered foreign food facilities to import food into the United States.

The proposed rule to establish the user fee program will create several categories of user fees:

1. Application Fee for ABs Applying for Recognition - $35,850
2. Application Fee for Recognized ABs Submitting Renewal Applications - $18,853
3. Application Fee for CBs Applying for Direct Accreditation - $35,850
4. Application Fee for CBs Applying for Renewal of Direct Accreditation - $26,930
5. Annual Fees for Recognized ABs - $1,585 to $1,878
6. Annual Fees for CBs Directly Accredited by FDA - $21,104
7. Annual Fees for CBs That Are Accredited by a Recognized AB - $1,982 to $2,250

The numbers to the right of the descriptions are estimates set forth in the Federal Register notice announcing the proposed rule. The Federal Register notice includes a detailed explanation of how the estimates were calculated.

The draft guidance sets forth model accreditation standards for third-party auditors and certification bodies. The standards include fairly detailed requirements in the following general areas as stated in the draft guidance:

A. Legal authority

A third-party auditor/certification body must show that it has the authority necessary to meet the accreditation requirements of proposed § 1.641, which sets forth the legal authorities FDA believes are necessary for thorough and credible audits and certifications under the program.

B. Certification authority and responsibility for

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A third-party auditor/certification body seeking accreditation must show that it has the authority (as a governmental entity or through contractual rights) to perform the assessments of facilities, their process(es), and food(s) necessary to determine compliance with the Food, Drug & Cosmetic Act (FDCA) and with industry standards and practices and to issue certifications where appropriate based on the assessments.

C. Capacity

In general, a third-party auditor/certification body seeking accreditation must show that it has the resources necessary to implement its third-party auditor program, including (1) adequate personnel (e.g., audit agents, managers) with the knowledge, skills, and experience to effectively audit and assess compliance with applicable FDA requirements and industry standards and practices and to issue valid and reliable certifications and (2) adequate financial resources for its operations.

D. Management and audit agent competence

This section elaborates on the education, experience, personal attributes, and training the third-party auditors' personnel must have to satisfy to audit and assess compliance with applicable FDA requirements and industry standards and practices.

E. Conflicts of interest

A third-party auditor/certification body must show that it has a written program to protect against conflicts of interest between the third-party auditor/certification body (and its officers, personnel, and other agents) and eligible entities certified or seeking certification.

F. Quality assurance

A third-party auditor/certification body must show the capability to meet the quality assurance requirements of proposed § 1.655, including periodic self-assessment; the ability to quickly implement effective corrective actions, if areas needing improvement are identified; and preparation of a written report in English of the results of the self-assessment.

G. Records procedures

A third-party auditor/certification body seeking accreditation must show that it has implemented written procedures to establish, control, and retain records for a period of time necessary to meet its contractual and legal obligations and to provide an adequate basis for assessing its program and performance.

H. Documentation of competence

A third-party auditor/certification body must show that it has implemented written procedures to establish and maintain records to provide a basis for assessing its third-party auditor program and performance (see proposed § 1.645(a)).

I. Regulatory audit reports

An accredited auditor/certification body must, within 45 days of

completing a regulatory audit, prepare and submit electronically, in English, to FDA (and where applicable to its accreditation body) a report of such regulatory audit that includes certain information set forth in the draft guidance.

J. Publicly accessible information and directory of certified clients

An accredited third-party auditor/certification body must maintain on its Web site an up-to-date list of the eligible entities to which it has issued food or facility certifications. For each such eligible entity, the Web site must also identify the duration and scope of the certification and the date(s) on which the eligible entity paid the third-party auditor/certification body any fee or reimbursement associated with the certification.

K. Certification documents

For submission to FDA, a third-party auditor/certification body must issue food or facility certifications electronically and in English containing certain elements set forth in the draft guidance.

A copy of the draft guidance document, which sets forth the standards in greater detail, can be found here. Comments on the proposed rule and draft guidance are due October 7, 2015.

For more information, please contact the Barnes & Thornburg LLP attorney with whom you work or one of the following attorneys in the firm's Food, Drug & Device Group: Lynn Tyler at (317) 231-7392 or lynn.tyler@btlaw.com; or Hae Park-Suk at (202) 408-6919 or hae.park.suk@btlaw.com.

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