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Regulatory Alert: FDA Releases Model Accreditation Standards for the Third-Party Auditor Rule and Estimated User Fees

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On July 23, 2015, the U.S. Food and Drug Administration (FDA) released draft Model Accreditation Standards for Third-Party Auditor /Certification Body Accreditation ("Model Accreditation Standards") pursuant to the Food Safety Modernization Act (FSMA). FDA also released a proposed rule on user fees for participation in the program. Please contact Erik Lieberman at erl1@liebermanpllc.com or 202.830.0300 if you have questions or would like additional information. Lieberman PLLC assists firms in FSMA compliance and managing regulatory risks.

Background

Section 307 of FSMA required FDA to establish a program to accredit third-party auditors and certification bodies (CBs) to perform food safety audits for purposes of certifying that facilities, farms and foods comply with applicable provisions of the Federal Food, Drug and Cosmetic Act. Exports from a facility or farm that is certified by an accredited third-party auditor or CB are eligible to be imported pursuant to the Voluntary Qualified Importer Program (VQIP) which expedites entry of goods at the U.S. border. Importers seeking to participate in VQIP must apply and be approved by FDA.

FDA was given authority to require import certifications under FSMA for certain high-risk foods exported by countries with food safety systems determined to be inadequate by the Agency. Accredited third-party auditors/CBs have authority to issue these import certifications. A summary of the Model Accreditation Standards for third-party auditors and CBs and estimated user fees for participation in the program follows.

Key Points

Model Accreditation Standards

ISO/IEC 17021: FDA was guided in development of the Draft Model Standards by the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) ISO/IEC 17021: *Conformity Assessment—Requirements for bodies providing audit and certification management systems* (2011).

Authority and Responsibility

- **Legal Authority:** Third-party auditors/CBs must demonstrate that they have sufficient legal authority to meet the standards in the Third-Party Auditor Rule including authority related to records access, onsite audits, and issuing, suspending or withdrawing certification.

- **Certification Authority:** Third-party auditors/CBs must demonstrate they have authority (as a government entity or through contractual rights) to perform assessments of facilities, their processes and foods.

Capacity and Competence

- **Capacity:** A third-party auditor/CB may range in size from a single person operation to a large organization. Auditors/CBs must have adequate numbers of personnel and adequate financial resources for operations.
- **Management and Audit Agent Competence:** A third-party auditor/CB must demonstrate that its personnel and audit agents have relevant knowledge, skills and experience to perform their responsibilities. Prerequisites and training standards for audit agents and managers are specified in the Model Accreditation Standards.
- **Audit Agent Evaluation and Monitoring:** Third-party auditors/CBs should have a documented process for performing initial and on-going evaluations, and on-going monitoring of audit agents. The frequency for the performance and skills evaluation is specified in the Model Accreditation Standards.

Conflicts of Interest: Third-party auditors/CBs must demonstrate that they can meet the conflict of interest standards in the Third-Party Auditor Rule. A written conflict of interest program is required. Such a program should include measures for promoting independence, objectivity and impartiality.

Quality Assurance: Third-party auditors/CBs must demonstrate the capability to meet the quality assurance standards in the Third-Party Auditor Rule. Annual reviews of management systems are encouraged.

Records

- **Records Procedures:** Third-party auditors/CBs must demonstrate that they have implemented written recordkeeping procedures to meet the standards in the Third-Party Auditor Rule.
- **Written Conflict of Interest Program:** FDA states the specific requirements that a third-party auditor/CB must have. These requirements parallel the requirements in the Third-Party Auditor Rule.
- **Documentation of Competence:** A third-party auditor/ CB must demonstrate that it has implemented written procedures to establish and maintain records to provide a basis for assessing its third-party auditor program and performance.

Regulatory Audit Reports: The Model Accreditation Standards recite the requirements for content of regulatory audit reports in the Third-Party Auditor Rule.

Miscellaneous:

- **Publically Accessible Information and Directory of Certified Clients:** An accredited auditor/CB must maintain on its website an up-to-date list of entities to which it has issued food

or facility certifications and other related information consistent with the requirements in the Third-Party Auditor Rule.

- **Certification Documents:** Consistent with the Third-Party Auditor Rule, certification documents must be issued electronically and in English.

User Fees

FDA's proposed rule establishing user fees for participation in the Accreditation of Third-Party Auditor Program estimates the following fees:

- **Accreditation Bodies**
  - Initial Application Fee: $35,850
  - Renewal Application Fee: $18,853
  - Annual fee: $1,585-$1,878
- **Certification Bodies**
  - Initial Application Fee: $35,850 (for direct FDA accreditation)
  - Renewal Application Fee: $26,930 (for direct FDA accreditation)
  - Annual Fee: $21,104 (for direct FDA accreditation)
  - Annual Fee: $1,982-$2,250 (CB accredited by an FDA-recognized AB)

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