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Regulatory Alert: FDA Releases Final Rule on FSMA Third-Party Auditor User Fees

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On December 14, 2016, the U.S. Food and Drug Administration (FDA) published a final rule entitled Amendments to Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications to Provide for the User Fee Program (the "Final Rule"). The Final Rule is effective January 13, 2017, and provides for a user fee program to assess fees for the work FDA performs to establish and administer the third-party certification program under the FDA Food Safety Modernization Act (FSMA).

Under the Final Rule, FDA will suspend recognition of accreditation bodies that fail to pay their annual user fee within 30 days of the payment due date, and revoke it within 90 days. Similarly, FDA will suspend accreditation of third-party certification bodies who do not pay their annual fee within 30 days of the payment due date, and revoke it within 90 days. FDA will notify the public of revocations and suspensions.

Certificates issued for purposes of Voluntary Qualified Importer Program (VQIP) eligibility can only be issued by third-party auditors/certification bodies accredited pursuant to FDA's third-party certification program.

Parties subject to user fees include:

1. Accreditation bodies submitting applications or renewal applications for recognition in the third-party certification program;
2. Recognized accreditation bodies participating in the third-party certification program;
3. Third-party certification bodies submitting applications or renewal applications for direct accreditation; and
4. Accredited third-party certification bodies (whether accredited by recognized accreditation bodies or by FDA through direct accreditation) participating in the third-party certification program.

On December 14, 2016, FDA also issued a notice announcing the fiscal year 2017 fee schedule for work FDA performs related to implementing the FSMA third-party certification program. The fees are as follows:

- Hourly rate without travel: **$204**
- Hourly rate if travel is required: **$285**
- Renewal application fee for recognized accreditation body: **$18,855** (estimated)

- Initial application fee for certification body seeking direct accreditation from FDA: **$35,100** (estimated)
- Renewal application fee for directly-accredited certification body: **$26,460** (estimated)
- Annual fee for recognized accreditation body: **$1,579** (estimated)
- Annual fee for certification body directly-accredited by FDA: **$20,208** (estimated)
- Annual fee for accredited certification body: **$1,974** (estimated)

Please contact Erik Lieberman at erl1@liebermanpllc.com or 202.830.0300 if you have questions or would like additional information