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FDA Proposes User Fees and Model Accreditation Standards for Accreditation Bodies and Third-Party Auditors/Certification Bodies under FSMA

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Food & Drug

On Friday, July 24, 2015, FDA announced in the Federal Register a proposed user fee program, under the Food Safety Modernization Act (FSMA), to collect fees for accrediting and monitoring accreditation bodies (ABs) and third-party auditors/certification bodies (CBs).[1] The regulation establishing the user fee program would accompany the regulation in the proposed FSMA rule, "Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications" (Accreditation of Third-Party Auditors proposed rule).

FDA also issued draft guidance that, when finalized, will contain FDA recommendations on third-party auditor/certification body qualifications for accreditation to conduct food safety audits and to issue food and/or facility certifications under FSMA.[2]

FDA is accepting comments on both documents through October 7, 2015.

FDA's User Fees Would Not Apply (Directly) to Food Producers

Because the proposed user fees apply directly only to ABs (the entities that would be accrediting the CBs) and to CBs (the entities conducting foreign food safety audits and issuing certifications), the fees would not apply to food, beverage, or dietary supplement manufacturers or distributors, except that such fees ultimately may be passed on to these companies indirectly as part of the cost of obtaining services from the CBs.

Background of Proposed User Fees and Model Accreditation Standards

FSMA requires FDA to set up, by regulation, a user fee program to assess fees to reimburse it for the costs of establishing and administering the third-party accreditation program pursuant to that law. Under the third-party accreditation program, FDA expects to use the certifications issued by the accredited CBs principally in deciding: (1) whether to admit certain imported food

[1] *See* Proposed Rule, User Fee Program To Provide for Accreditation of Third-Party Auditors/Certification Bodies To Conduct Food Safety Audits and To Issue Certifications, 80 Fed. Reg. 43987 (July 24, 2015).
[2] *See* Third-Party Auditor/Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards; Draft Guidance for Industry and Food and Drug Administration Staff, 80 Fed. Reg. 44137 (July 24, 2015).

into the U.S. that FDA has determined poses a food safety risk; and (2) whether an importer is eligible to participate in FDA's Voluntary Qualified Importer Program (VQIP) for expedited review and entry of food imports.[3]

FSMA also requires FDA to develop Model Accreditation Standards that ABs must use to accredit CBs. In developing the Model standards, FDA must look at existing standards to avoid unnecessary duplication of efforts and costs.

Proposed User Fee Program

The proposed rule would establish a user fee program under which FDA would assess and collect application and participation fees from ABs and CBs. While FDA would establish these fee rates each year based on the most recently available data and publish the fee rates in the Federal Register before the start of each year, the proposed rule includes the methods that FDA has proposed to use to calculate these fees, as well as estimates of the fees based on current financial data and participation estimates. These fees, FDA's estimates, and proposed methodologies are summarized in the table below. FDA specifically requests comments on its proposed fee calculation methods and alternative methods. The proposed fees include application fees (to fund FDA's review of the applications) and annual fees (to fund FDA's monitoring activities under the program).[4]

Proposed Fees for Accreditation Bodies (AB) (Flat rate fee)	
AB initial application fee	$35,850/application*
AB renewal application fee	$18,853/application*
AB annual fee	$1,585 - $1,878^ (the annualized amount, depending on inflation)
Proposed Fees for Certification Bodies (CBs) (Flat rate fee)	
CB direct (FDA) accreditation application fees	$35,850*
CB direct (FDA) accreditation renewal application fees	$26,930*
CB direct (FDA) accreditation annual fees	$21,104
CB annual fees (accredited by a recognized AB)	$1,982 - $2,250^ (annualized amount, depending on inflation)

*For application fees, FDA also proposed other fee methods, including: (1) an alternative fee--FDA could bill each applicant separately for the actual application costs attributable to it (to incentivize submission of higher quality applications that are easier/faster to review); and (2) a hybrid fee--a combination of the alternative fee (e.g., for onsite audit) plus a flat rate fee (e.g., for paper application review).

[3] 80 Fed. Reg. at 43988. To view Covington's alert "FDA Releases Draft Guidance for Industry on Voluntary Qualified Importer Program for Food" (June 9, 2015), please click here.
[4] *Id.* at 43989.

^For annual fees, FDA proposed other fee methods: (1) a non-annualized fee--a single fee paid in the year it is due (e.g., every 4 or 5 years, depending on time frame for fee assessment); and (2) an annualized fee based on the term of recognition for each AB or CB (e.g., 2 or 3 year term (higher annual fee) versus a 4 or 5 year term (lower annual fee), depending on the time frame for the fee assessment).

Under the proposed rule, there would be no exemption or reduced fees for small businesses because no statutory exemptions, reductions, or requirements exist in the authorizing statute.[5] FDA notes in the proposed rule that the proposed fees would not cover all the costs associated with the establishment and administration of the third-party accreditation program.[6]

FDA's Draft Guidance on Model Accreditation Standards

In drafting the proposed Model Accreditation Standards, FDA sought to identify and rely on the standards most commonly used in qualifying CBs for conducting food safety audits, and therefore was guided 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) (ISO/IEC Standards).

The Model standards apply only to FDA staff that will be monitoring ABs and CBs, to ABs that will be accrediting CBs, and to CBs that will be conducting food safety audits of foreign facilities. The Model standards do not apply to the activities of food producers or distributors.

The Model standards generally cover requirements for: the CBs physical capacity to conduct audits; the skill, knowledge, education, and experience of auditors to assess compliance with FDA food safety requirements; training requirements; evaluations and monitoring of auditors; conflicts of interest; quality assurance; audit reports; and certification documents.

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[5] *Id.* at 43995.
[6] *Id.* at 43989. FDA indicates it would bear the costs of reconsiderations of application denials or waiver requests, reviewing waiver requests, revocation of AB recognition, withdrawal of CB accreditation, maintaining website of recognized ABs and accredited CBs, and the general initial startup costs (i.e., training new employees and establishing IT systems).