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MEMORANDUM

From: Gary Jay Kushner
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Re: **FDA Proposes User Fees and Issues Model Standards for Third-Party Accreditation Under FSMA**

Today, the Food and Drug Administration (FDA) published two new documents to support the development of a program to accredit third-party auditors and certification bodies under the FDA Food Safety Modernization Act (FSMA). First, FDA issued a proposed rule to establish user fees for the third-party auditor accreditation program. 1/ Second, FDA published draft guidance that sets forth Model Accreditation Standards (MAS) for the program. 2/ Both documents relate to the proposed rule on third-party certification for imported foods, which was issued July 29, 2013. 3/ FDA is under a court order to finalize that regulation by October 31, 2015. Comments on the proposed rule and draft guidance are due October 7, 2015.

Background

Under FSMA, FDA may require that foods offered for import into the United States be accompanied by a certification issued by an accredited third-party in two circumstances. First, such certifications can be required for foods identified by FDA as posing a high risk under FSMA section 303. When determining if foods present a high risk for this purpose, FDA is required to take account of the following factors:

- Known safety risks associated with the food;
- Known food safety risks associated with the country, territory, or region of origin of the food;
- A finding by FDA, supported by scientific, risk-based evidence, that—
  - the food safety programs, systems, and standards in the country, territory, or region of origin of the food are inadequate to ensure that the article of food is as safe as a similar article of food that is manufactured, processed, packed, or held in the United States; and
  - the certification would assist FDA in determining whether to refuse or admit the article of food; and
- Other information submitted to FDA by a foreign food safety authority.

1/ 80 Fed. Reg. 43987 (July 24, 2015).
2/ 80 Fed. Reg. 44137 (July 24, 2015).
3/ *Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications*; Proposed Rule; 78 Fed. Reg. 45782 (July 29, 2013); *see* Hogan Lovells memorandum, *FDA Releases FSMA Proposed Rule on Third Party Accreditation* (Aug. 2, 2013).

FDA has not yet advised on the types of foods expected to receive a "high risk" classification for this purpose, but the scope is generally expected to be narrow because the statute sets a high standard.

Second, foreign facilities that manufacture food imported to the United States under the Voluntary Qualified Importer Program (VQIP) must be certified by an accredited third-party auditor. Importers participating in VQIP also must meet designated criteria and pay an associated participation fee. FDA issued draft guidance on VQIP in June 2015. 4/

Proposed Rule on User Fees

FDA proposes charging fees to accreditation bodies (ABs) and certification bodies (CBs) when they submit applications to the program and apply for renewal. Additionally, annual fees would apply to ABs and CBs for the estimated cost of the work FDA would perform monitoring their activities. The preamble to the proposed rule includes a detailed explanation of the basis for FDA's fee estimates. The initial estimated fees are as follows:

	Accreditation Bodies	**Certification Bodies**
Initial Application	$21,210	$21,210
Initial Application if Foreign Travel is Needed	$35,850	$35,850
Renewal Application	$18,853	$26,930
Annual Fee 5/	$1,585 to $1,878 (based on inflation)	$21,104 if directly accredited by FDA $1,982 to $2,250 if accredited by a recognized AB (based on inflation)

FDA is considering several alternative approaches to assessing fees. In particular, FDA is considering billing each applicant for the actual amount of time FDA takes to review and evaluate the particular applicant's application or renewal application. The agency is requesting comments on this approach and, in particular, on whether this would result in higher quality application submissions.

FDA notes in the preamble that it is "wary that a high application fee could deter participation in the program," and explains its reasoning behind the fees and the alternative approaches that were considered. FDA requests comments on the proposed fee structure, the alternatives discussed in the preamble, and any other alternative fee structures that may be simpler or more consistent with industry practice.

FDA would notify the public of the fee schedule annually prior to the beginning of the fiscal year in which the fees would apply. The fee would be required to be submitted concurrent with applications, and applications would not be reviewed until fees are paid. Further, if an AB or CB fails to submit its user fee within 30 days, its recognition/accreditation would be suspended. Any CB accredited by the AB prior to the suspension would not be affected by the suspension, nor would any food or facility certification issued by such CB. Failure to pay within 90 days would result in revocation of an AB's recognition or a CB's accreditation.

4/ *See* Hogan Lovells memorandum, *FDA Issues Draft Guidance on the FSMA Voluntary Qualified Importer Program* (June 16, 2015).

5/ FDA assumes an average term of recognition of 5 years.

Fees would not be refundable. Additionally, there would be no exemption or reduced fee for small businesses or entities. Finally, FDA proposes charging user fees to foreign government entities that are applying to and participating in the program as either an AB or CB, but requests comments on whether it should consider a different approach for trade reasons.

Model Accreditation Standards

FDA's draft guidance sets forth FDA's MAS that recognized ABs would use to qualify third-party auditors or CBs for accreditation. Development of these standards is required under FSMA. The law also directs FDA to look to existing standards to avoid unnecessary duplication. Accordingly, development of FDA's draft standards was guided by International Organization for Standardization (ISO) / International Electrotechnical Commission (IEC) ISC/IEC 17021: *Conformity Assessment – Requirements for bodies providing audit and certification management systems* (2011) ("ISO/IEC 17021:2011"). Substantively, the MAS draft guidance addresses issues such as auditor capacity and competence, conflicts of interest, quality assurance, records, and regulatory audit reports.

When it is finalized, FDA's MAS guidance will be a "companion" to the forthcoming final rule on third-party accreditation under FSMA. However, because the final rule has not yet been published, the draft MAS reflect and reference the requirements FDA proposed in July 2013. Accordingly, the document does not incorporate any revisions to the proposed rule that reflect comments on the proposal. Thus, the MAS references requirements for auditors from the proposed rule that industry objected to, including the requirement for auditors to report to FDA any conditions that could cause or contribute to a Class I or Class II recall if observed during a regulatory or consultative audit. The final MAS guidance will need to align with the forthcoming third-party accreditation final rule, when published. Therefore, we can expect revisions to the draft guidance on MAS after the final rule is issued.

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We will continue to monitor FDA's implementation of FSMA. Should you have any questions, please do not hesitate to contact us.