

MEMORANDUM

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Re: FDA Announces Reinspection and VQIP Fees for Fiscal Year 2020

The Food and Drug Administration (FDA) recently announced its Fiscal Year (FY) 2020 fee rates, which in particular cover the fees for facility reinspections and participation in the Voluntary Qualified Importer Program (VQIP). ^{1/} These fees were authorized by the FDA Food Safety Modernization Act (FSMA) and were first implemented in October 2011 (for FY 2012). ^{2/} Reinspection fees are charged when FDA performs an inspection subsequent to an inspection that identified a “non-compliance materially related to a food safety requirement of [the Federal Food, Drug, and Cosmetic Act], specifically to determine whether compliance has been achieved.” VQIP is a voluntary, fee-based program that provides expedited review and import entry of human and animal foods into the United States for participating importers.

Fees for Facility Reinspections, Importer Reinspections, and Failures to Comply with a Recall Order

For facility reinspections, importer reinspections, and failures to comply with a recall order, the hourly, per person, rates for FY 2020 are \$258 if domestic travel is required and \$301 if foreign travel is required. The rates are slightly higher than in 2019. ^{3/} The new rates will be effective from October 1, 2019 through September 30, 2020.

Notably, FDA is continuing to refrain from issuing any invoices for reinspection or recall order fees until it has published a guidance document to outline the process through which small businesses may request a reduction of fees. Therefore, although facility reinspection fees are currently in effect, food companies of all sizes should not expect to receive invoices for reinspections until this guidance is issued.

Additionally, FDA advises that they continue to consider various issues associated with the assessment and collection of importer reinspection fees. The agency announced in Guidance issued in 2011 that importer reinspection fees will not be assessed until the agency has resolved “particular complexities” raised in comments regarding these fees. ^{4/} FDA explains that the rates set

^{1/} 84 Fed. Reg. 35680 (July 24, 2019), 84 Fed. Reg. 35872 (July 25, 2019).

^{2/} FSMA § 107.

^{3/} 83 Fed. Reg. 35659 (July 27, 2018).

^{4/} *Guidance for Industry: Implementation of the Fee Provisions of Section 107 of the FDA Food*

forth in the fee schedule will be used to determine any importer reinspection fees assessed in FY 2020.

Fees for VQIP

The VQIP user fee is \$16,681. In addition, there are fees related to FDA's inspection of the foreign facility. The hourly, per person, rates for FY 2020 are \$240 if no travel is required, \$258 if domestic travel is required, and \$301 if foreign travel is required.

This notice is the first time that FDA has published the fee rates for VQIP. At this time, FDA is not offering an adjusted fee for small businesses, but the Notice states that FDA plans on monitoring costs and collecting data to determine if, in future fiscal years, the agency will provide for a small business fee reduction.

These fees are effective August 1, 2019, and will remain in effect through December 31, 2019. ^{5/} Invoices must be paid prior to October 1, 2019 in order to be eligible for VQIP participation for the year beginning October 1, 2019. Additionally, for a subsequent year, if the user fee is not paid before October 1, FDA will send a "Notice of Intent to Revoke" participation in VQIP. If the user fee is not paid within 30 days of the date of the Notice of Intent to Revoke, FDA will revoke participation in VQIP.

The portal for VQIP applications for FY 2020 is open through July 31, 2019. Thereafter, the portal will remain closed until January 2020, when FDA will begin accepting applications for FY 2021. Participation in VQIP requires certification by an accredited certification body under FDA's accredited third-party certification program.

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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.

Safety Modernization Act, September 2011.

^{5/} The FY 2020 VQIP user fee will support benefits from October 1, 2019, through September 30, 2020.