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Regulatory Alert: FDA Announces FSMA Fees for Fiscal Year 2018

Fee Increased for Domestic Activities, Remains the Same for Foreign Activities

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On August 2, 2017, the U.S. Food and Drug Administration (FDA) published in the Federal Register the Domestic and Foreign Facility Reinspection, Recall and Importer Reinspection Fee Rates for Fiscal Year 2018. **The fees are $248 per hour if domestic travel is required and $285 per hour if foreign travel is required.** The fees are effective on October 1, 2017, and will remain in effect through September 30, 2018.

For FY2017 the fees for domestic activities were $221 per hour and for foreign activities $285 per hour.

Section 107 of FSMA added section 743 (21 USC § 379j-31) to the Federal Food, Drug and Cosmetic Act (FDCA) to provide FDA with the authority to assess and collect fees from in part: (1) The responsible party for each domestic facility and the U.S. agent for each foreign facility subject to a reinspection to cover reinspection related-costs; (2) the responsible party for a domestic facility and an importer who does not comply with a recall order, to cover food recall activities associated with such order; and (3) each importer subject to a reinspection to cover reinspection related costs.

The fees will be assessed for a reinspection conducted under section 704 (21 USC § 374) of the FDCA to determine whether corrective actions have been implemented and are effective and compliance has been achieved to FDA's satisfaction at a facility necessitated as a result of a previous inspection (also conducted under section 704) of such facility, which had a final classification of Official Action Indicated (OAI) conducted by or on behalf of FDA, when FDA determined the non-compliance was materially related to food safety requirements of the FDCA. FDA considers such non-compliance to include violations of a statutory or regulatory requirement under sections 402 (adulteration) and 403(w) (food allergen labeling) of the FDCA.

The fees will also be assessed for not complying with a recall order under section 423(d) (21 U.S.C. § 350l(d)) or section 412(f) of the FDCA (21 U.S.C. § 350a(f)). Non-compliance may include the following: (1) Not initiating a recall as ordered by FDA; (2) not conducting the recall in the manner specified by FDA in the recall order; or (3) not providing FDA with requested information regarding the recall, as ordered by FDA.

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