

Regulatory Alert: FDA Announces FSMA Fees for Fiscal Year 2017

Fee Remains Unchanged for Domestic Reinspections, Reduced for Foreign Reinspections

August 1, 2016

On August 1, 2016, 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 2017](#). **The fees are \$221 per hour if domestic travel is required and \$285 per hour if foreign travel is required.** The fees are effective on October 1, 2016, and will remain in effect through September 30, 2017.

For FY2016 the fees for domestic reinspections were \$221 per hour and for foreign reinspections \$315 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 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.

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