

## FSMA ALERT

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### Pursuant to FSMA, FDA Announces FY 2015 Reinspection Fees

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On July 31, 2014, the Food and Drug Administration (FDA) published fee rates for fiscal year 2015 for certain domestic and foreign facility reinspections, failures to comply with a recall order and importer reinspections. The new fees will be effective on **October 1, 2014** through **September 30, 2015**.

The Food Safety Modernization Act (FSMA) added §743 to the Food, Drug and Cosmetics Act (FDCA), granting FDA the authority to assess and collect fees from:

- the responsible party for each domestic facility and the U.S. agent for each foreign facility subject to reinspection to cover reinspection-related costs;
- the responsible party for a domestic facility and any importer who does not comply with a recall order to cover food recall activities associated with such order; and
- each importer subject to a reinspection to cover reinspection-related costs.

The meaning given by FDA to the term “reinspection” can be summarized as the one or more inspections that might be conducted subsequent to an inspection already conducted which identified a domestic or foreign company as non-compliant with FDA’s food safety requirements.

These fees will be based on the number of hours spent on each reinspection and actions taken to respond to the firm’s failure to comply with a recall order and will be billed at a rate of \$217 per hour for domestic reinspections and responses to non-compliance with a recall, and at \$305 per hour for foreign reinspections.

With regard to small companies, FDA will issue a guidance to address the process for which firms may request fee reductions and until such guidance is published, no invoices will be issued to these companies.

If you have questions regarding FSMA, food safety or FDA in general, please contact [Edgar Asebey-Birkholm](#), Food & Drug Practice Group Manager at 954.759.2754 or [easebey@ralaw.com](mailto:easebey@ralaw.com).