

Information Sheet – Assessment of Reinspection and Recall Fees by the FDA

The Federal Food, Drug, and Cosmetic (FD&C) Act, as amended by the FDA Food Safety Modernization Act (FSMA) (P.L. 111-353), authorizes FDA to collect and use fees to cover 100 percent of FDA's costs for: (1) certain reinspections of domestic and foreign facilities; and (2) certain food and feed recall activities beginning in the current fiscal year (FY) and each subsequent fiscal year. For more detailed information on fee setting for the reinspection and recall user fees for the current FY rates and to obtain answers to frequently asked questions about FSMA, please go to the following FDA website: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm>

When will the Fee be assessed by the FDA?

For the current Fiscal year User Fees will be assessed by the FDA under the following circumstances:

- (1) **Fee for Reinspection of Domestic and Foreign Facilities:** The fee will be assessed for a reinspection of domestic and foreign facilities conducted under the Federal Food, Drug, and Cosmetic (FD&C) Act to determine whether corrective actions have been implemented and are effective and compliance has been achieved to FDA's satisfaction, as a result of a previous inspection of this facility that had a final classification of Official Action Indicated (OAI) conducted by or on behalf of FDA, when FDA determined the noncompliance was materially related to food safety requirements of the FD&C Act.
 - a. Section 743(a)(2)(A)(i) of the FD&C Act defines the term "reinspection" with respect to domestic facilities as "1 or more inspections conducted under section 704 subsequent to an inspection conducted under such provision which identified non-compliance materially related to a food safety requirement of the Act, specifically to determine whether compliance has been achieved to the Secretary's satisfaction."
 - b. The FD&C Act does not contain a definition of "reinspection" with respect to foreign facilities. In order to give meaning to section 743(a)(1)(A) of the FD&C Act, FDA defines the term "reinspection," for the purposes of section 743(a)(1)(A) of the FD&C Act, with respect to foreign facilities as "1 or more inspections conducted by officers or employees duly designated by the Secretary subsequent to such an inspection which identified non-compliance materially related to a food safety requirement for the FD&C Act, specifically to determine whether compliance has been achieved to the Secretary's (and, by delegation, FDA's) satisfaction."

The fee charged by FDA will be based on the number of direct hours spent on such reinspections, including time spent conducting the physical surveillance and/or compliance reinspection at the facility, or whatever components of such an inspection are deemed necessary, making preparations and arrangements for the reinspection, traveling to and from the facility, preparing any reports, analyzing any samples or examining any labels if required, and performing other activities as part of the OAI reinspection until the facility is again determined to be in compliance. The direct hours spent on each such reinspection will be billed at the appropriate hourly rate which can be found at the following link: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm>

The Federal Register announcement for the Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2015 may be found at the following link: <http://www.regulations.gov/#!documentDetail;D=FDA-2013-N-0007-0014>

- (2) **Fee for Non-compliance with a Recall Order:** FDA will assess a fee for non-compliance with a recall order under Section 423(d) or 412(f) of the FD&C Act to cover food recall activities associated with such order. Non-compliance may include (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 the FDA.
 - a. Section 743(a)(1)(B) of the FD&C Act states that the fee is to be paid by the responsible party for domestic facilities and an importer who does not comply with a recall order under Section 423(d) or 412(f) of the FD&C Act. In other words, the party paying the fee would be the party that received the recall order.

The fee is based on the number of direct hours spent on taking action in response to the firm's failure to comply with a recall order. Types of activities could include conducting recall audit checks, reviewing periodic status reports, analyzing the status reports and the results of the audit checks, conducting inspections, traveling to and from locations, and monitoring product disposition. The direct hours spent on each such recall will be billed by the FDA at the appropriate hourly which can be found: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm>