

FSMA User Fees: The Cost of Non- Compliance

While FDA is currently collecting fees for any reinspections resulting from an initial inspection that occurred after October 1, 2011 and failure to comply with any recall orders issued after October 1, 2011, the Agency has said it needs more time to determine the process and mechanism for collecting import-related fees.

FDA established that they will charge user fees of \$224 an hour if no foreign travel is required and \$335 an hour if foreign travel is required. Table 1 outlines how the Agency established the fee schedule.

Charging the user fees on an hourly rate means that the responsible party (facility or importer) will be charged based on time which likely translates to the severity of the problem and the ability to clearly and easily document and demonstrate that the appropriate actions have been implemented.

As of October 1, FDA is authorized to collect the new user fees outlined in the Food Safety Modernization Act (FSMA), which include:

1. Failure to comply with recall orders;
2. Reinspection-related costs; and
3. Importer reinspection-related costs.

Table 1: FDA FSMA User Fee Rates

\$207	8.42%	\$224
Average cost per hour (excluding the cost of foreign inspection travel) *	Compound Inflationary adjustment factor of 4.53% for FY 2011 and 3.72% for FY 2012 =	FSMA Fee hourly rate if no foreign travel is required
\$224	\$101	\$335
FSMA Fee hourly rate if no foreign travel is required †	Adjusted additional cost per hour for foreign inspections =	FSMA Fee hourly rate if for- ign travel is required

Recalls:

What will cause the fee to be assessed? FDA is authorized to assess fees for failure to comply with a recall order. Failure to comply could include not initiating a recall as ordered by FDA, not conducting the recall in the manner ordered, or not providing information to FDA as ordered.

Who is responsible for paying the fee? The party that receives the recall order (responsible party for a domestic facility or an importer).

How much is the fee? The fee will depend on the number of hours spent directly on the recall, e.g. recall audit checks, reviewing reports, analyzing reports, conducting inspections, traveling to and from locations, and monitoring disposal of product.

NOTE: Prior to issuing a recall order and assessing any user fees, the Agency must provide the responsible party with the option of voluntarily recalling the product.

Reinspections:

What will cause the fee to be assessed? A fee will be assessed if FDA conducts a facility reinspection – defined as “an inspections conducted subsequent to such an inspection which identified non-compliance material related to a food safety requirement of the FD&C Act.” FDA notes that fees will only be assessed for reinspections of facilities that have a final designation of “Official Action Needed (OAI)” on an initial inspection related to food safety requirements.

Who is responsible for paying the fee? The responsible party for the registered facility or the U.S. agent for a foreign facility will be accountable for paying any fees.

How much is the fee? The fee will depend on the number of hours spent directly on the reinspection, e.g. physical surveillance or compliance reinspection at the facility, making preparations and arrangements for the reinspection, traveling to and from the facility, preparing reports, analyzing samples, or examining labels.

The best strategy to avoid paying reinspection user fees will be to ensure that your facility is in compliance to start with but if you do find yourself in a non-compliance situation, have clear documentation of all corrective actions to ensure the reinspection takes the minimal amount of time possible.

Import Reinspection/Examination:

FDA is still deliberating this part of the fee structure but FDA identified at least four scenarios where fees will be assessed for import reinspection/examination when non-compliance materially related to food is found.

1. Reconditioning of food found to be in violation of the Food, Drug and Cosmetic Act to bring it into compliance by, for example, re-labeling or heat treatment. Fees may be assessed for the time spent to review and approval of the request.
2. Importers seeking admission of an article that has been detained, including situations where product has been detained under an Import Alert. FDA may charge a user fee for the review of evidence submitted regarding admissibility.
3. Requesting removal from an Import Alert for Detention Without Physical Examination. When an entity seeks removal from an import alert, FDA will be able to charge user fees for the review of supporting documentation and any other related examinations to determine if compliance has been achieved to FDA’s satisfaction.
4. Destruction of food that have been refused admission to the U.S. If destruction of a refused product is conducted under the supervision of FDA or Customs and Border Protection, fees may be assessed. FDA may also charge user fees for time spend reviewing and approving destruction protocol.



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