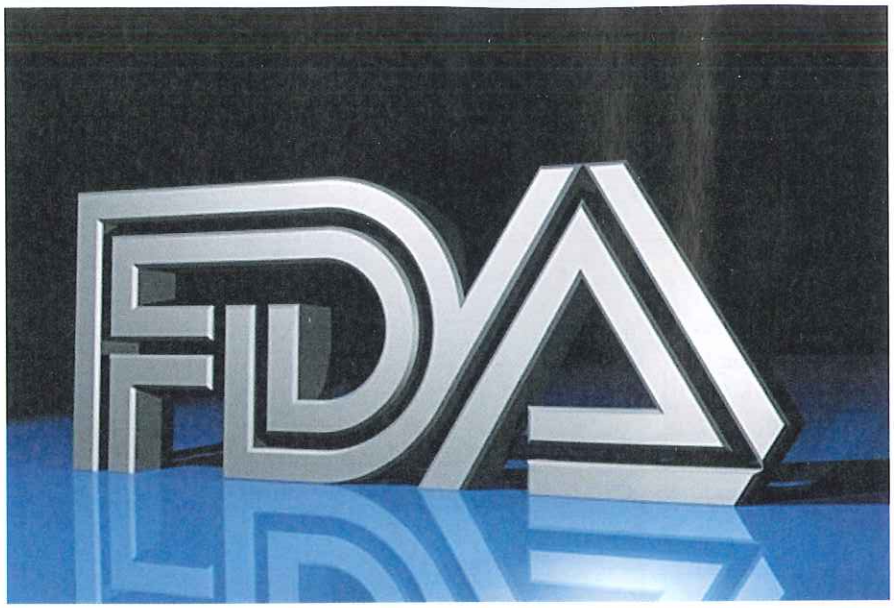

U.S. FDA Now Requiring Facility Re-Registration

Pursuant to the FSMA, all domestic and foreign facilities now have to re-register their facilities with the FDA.

By Don Pisano

As a legislative response to multiple instances of food, health care products and pet foods that were found to have been contaminated and hazardous to humans and animals, the U.S. Congress drafted the Food Safety Modernization Act (FSMA), considered to be the most sweeping reform of U.S. food safety laws in more than 70 years. It was signed into law by President Obama on January 4, 2011. With the objective of ensuring the safety of the U.S. food supply through preventative measures, the FSMA directs the FDA to mandate supply chain management controls on the food industry and set modern standards across the entire spectrum of imported and domestic food production, packaging and handling systems.

While providing for collaboration and transparency in public-private partnership, this new law strengthens the FDA's regulatory role with new inspection and enforcement tools. But it was left to the FDA to actually write the regulations required to comply with the wording and intent of the law.

Although the law has been in effect for two years now, the FDA has produced only limited new regulations and has much left to accomplish to fulfill its legislative mandate. But it did review the existing foreign and domestic food facility registration requirements, which had been developed and instituted to comply with the earlier Bioterrorism Act of 2002, expand on those requirements, assert increased compliance monitoring, and institute a cost recovery program. It also added new responsibilities and potential liability on the U.S. agent for foreign food facilities.

In August 2012, the FDA announced the new requirement that all domestic and foreign facilities would have to re-register their facilities with the FDA between October 1, 2012 and December 31, 2012 and then would be required to re-register those facilities every two years thereafter. As the deadline approached, and evidently recognizing the limited period allowed for such a significant global supply chain effort, the FDA announced that it would exercise discretionary enforcement through January 31, 2013, though technically not altering the deadline.

Another significant aspect of the FSMA was to provide the FDA with the authority to assess and collect fees from the responsible party for each domestic facility, and from the U.S. agent for each foreign facility, which may be subject to a re-inspection subsequent to an initial inspection that identified materially adverse conditions relating to food safety. The re-inspection will be called for to determine whether corrective actions have been implemented and compliance has been achieved to the FDA's satisfaction.

Although it is expected that few coffee or tea facilities would be subject to FDA re-inspections, the re-inspection costs are quite high so the risk is quite significant. The fees established for the fiscal year 2013 are at $221 per hour for U.S. facilities and $289 per hour for foreign facilities. These hourly rates will be assessed on the number of direct hours spent on the re-inspections including pre-inspection preparation, travel time, sample and label analysis and preparing any reports associated with the re-inspection.

Clearly the FDA does not want, nor have the capacity to pursue recovery of these fees against foreign food facilities. Thus, and as mentioned above, they will be looking to the U.S. agent for payment of these assessed fees. This is a significant change in the role and responsibility of the U.S. agent for foreign food facilities. Under the Federal Register Interim Final Rule - 68 FR 58893 of October 10, 2003: Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the original role of the U.S. agent was to act as a communications link between FDA and the foreign facility for both emergency and routine communications. The FDA would treat representations by the U.S. agent as those of the foreign facility, and consider information or documents provided to the U.S. agent the

equivalent of providing the information or documents to the foreign facility. Many importers, customs brokers and trade associations had assumed this role as a business accommodation to their suppliers, customers or membership, although often a modest fee.

With the announcement of the new FDA regulations, many of these U.S. Agents have grown concerned about the possibility that they may be assessed significant costs associated with a foreign facility re-inspection. What was once considered a business accommodation may now be considered a liability; and a responsibility they would prefer not to have, no matter how close a relationship they may have with their supplier. Consequently, many U.S. Agents have already decided to discontinue acting in this capacity. Others are limiting their agency to a select few and low risk facilities. This has left many foreign food facilities searching for new U.S. agents to act in this capacity, or discontinue shipments to the United States or through U.S. ports.

As there is not a handy directory of sorts available, most agents are sought out by means of referrals, often from their previous agents. Most agents who do perform this function as a primary business service have increased their rates to account for the higher risk being assumed. Also, they are usually performing the registration with the FDA themselves on behalf of the foreign facility, so that they, as agents, have a level of control of the information being registered.

All facilities that fail to re-register with the FDA will find their registrations expired. For all non-U.S. facilities, this includes having a valid designated U.S. Agent. Importers will need to ensure that their suppliers' FDA registration numbers are valid and current or they will be in non-compliance with current U.S. import regulations. And we need to get this done by January 31st or shipments can be subject to fines, detention or refusal of admission. A lovely way to start the new year in the coffee and tea business.

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