Industry Insights: FDA Sends First Warning Letter Under Recent Rule Regarding Imported Food

The Food Safety Modernization Act ("FSMA") ushered in a sea change in the government's regulation of food safety. Pursuant to FSMA, the FDA has promulgated a series of rules, including a 2015 rule related to the Foreign Supplier Verification Programs (the "FSVP Rule"). These programs set forth certain requirements to ensure food safety and appropriate labeling for food imported into the United States. The FSVP Rule requires that importers verify that the food they import into the United States has been produced in a manner that meets applicable U.S. food safety standards. Just this week, the FDA announced the issuance of its first warning letter under the FSVP Rule. The warning letter was sent to an importer of tahini, which was implicated in a Salmonella outbreak earlier this year. The tahini was recalled after four illnesses were reported. Per a statement attributed to Acting Commissioner Ned Sharpless, "The warning letter follows an FDA inspection conducted in response to a recent Salmonella outbreak, which revealed that the importer was not in compliance with the FSVP." The issuance of this warning letter indicates that the FDA will actively enforce the FSVP Rule and its required protocols for food products. The FDA has indicated that the agency will act "immediately" regarding the FVSP Rule when "deficiencies are found that pose an imminent public health risk." While certain foods and beverages are exempt from the FSVP Rule, food companies that import food are advised to consult FDA guidance documents regarding the rule and its enforcement and seek legal counsel as necessary in navigating the FSMA landscape. The FDA's statement about its recent warning letter is available here.

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