CHEESE IMPORTERS ASSOCIATION OF AMERICA

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CIAA Bulletin **An Exclusive CIAA Member Update**

FDA Issues First Warning Letter under FSVP Regulations

On July 30, 2019, the U.S. Food and Drug Administration (FDA) issued its first Warning Letter to an importer for violations of the Foreign Supplier Verification Program (FSVP) requirements at 21 C.F.R. Part 1, Subpart L (21 C.F.R. §§ 1.500 through 1.514). The Warning Letter was issued to a U.S. importer related to imported tahini implicated in a multi-state *Salmonella Concord* outbreak in spring 2019.

FDA stated in the Warning Letter that the importer was not familiar with the FSVP requirements, did not develop an FSVP for the imported tahini, and failed to respond to the FDA investigator's formal observations during the FSVP inspection. The Warning Letter also noted that the importer's voluntary recall, by itself, did not address the underlying FSVP violations.

This Warning Letter serves as an important reminder to importers that FDA expects companies to have FSVPs that meet the requirements of 21 C.F.R. Part 1, Subpart L.
FDA has been conducting FSVP inspections since 2017. These inspections have been primarily focused on assisting importers with understanding the FSVP requirements and how to take corrective actions for deficiencies. In Fiscal Year 2018, the failure to develop an FSVP was the most commonly cited observation in the food program.
In the Press Release accompanying the Warning Letter, FDA has stated that, going forward, FDA's focus will shift to ensuring compliance with the FSVP requirements. This will include re-inspecting importers that had deficiencies in previous inspections and taking immediate action when FSVP deficiencies are found that pose an imminent public health risk.

Importers that fail to take corrective actions for deficiencies identified by FDA during an inspection may also be subject to the newly established Import Alert #99-41,*Detention Without Physical Examination of Human and Animal Foods Imported from Foreign Suppliers by Importers Who Are Not in Compliance with the Requirements of the Foreign Supplier Verification Program (FSVP) Regulation*. Imports offered by an importer on the Red List under this Import Alert would be subject to automatic detention. Further, such

importers would be prevented from participating in the Voluntary Qualified Importer Program (VQIP).

We will continue to monitor developments related to FDA's implementation of the FSVP regulations. Should you have any questions regarding this alert, contact the Husch Blackwell LLP team at CIAAGeneralCounsel@huschblackwell.com.

Best regards,
Phil Marfuggi
President
CIAA

Dates to Remember

August 31, 2019
Last day to enter dairy products into U.S. Customs territory that may be used to qualify and establish eligibility for a calendar year 2020 license.

September 3, 2019
First day of 2020 license applications
Last day to request a globalization of a calendar year 2019 license

September 16, 2019
Last day of licensees applying for reallocated license amounts for 2019

October 1, 2019
Last day to surrender 2019 license amounts

October 15, 2019
Last day of 2020 license applications

November 7, 2019
Member Meeting
9:30 am - 11:30 am
Saddle Brook Marriott
Saddle Brook, NJ

***** If a deadline date falls on a Saturday, Sunday, or Federal holiday, the deadline will be the next business day (Section 6.36(a) of the Dairy Tariff-Rate Import Quota Licensing Regulation). This does not apply to dates of entry for eligibility.

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