

An Exclusive CIAA Member Update



FDA Guidance on Actions That Constitute a Refusal of Inspection at Foreign Food Facilities

The U.S. Food and Drug Administration (FDA) is clarifying what constitutes a refused inspection by foreign food establishments. On October 20, 2022, the FDA issued [guidance](#) outlining what types of actions and statements that it will consider as a refusal of an FDA inspection at a foreign food facility.

Under its Food Safety Modernization Act (FSMA) authority, FDA may deny entry of imported food into the U.S. if the food establishment or foreign government refuses to allow FDA to inspect the establishment that produced the food. The guidance provides FDA's interpretation of "refuses to permit entry ... to inspect" a foreign food establishment under section 807(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384c(b)).

CIAA recommends that this guidance is shared with foreign suppliers to enhance their understanding of FDA's expectations for inspections at foreign food facilities. Because a refusal can negatively impact imports from that facility, this communication is key to prevent interruptions to imports.

The guidance indicates that FDA will consider "statements, actions, and passive behaviors" to be refusals when they prevent or delay FDA from scheduling or conducting an inspection or when they are "intended to avoid inspection or to mislead or deceive the FDA investigator in a manner that prevents the investigator from conducting the inspection." The following actions by foreign food establishments as refusals of inspections:

- Failure by an owner, operator, or agent in charge of a foreign food establishment to respond within 24 hours after a written inspection request.
- Failure to communicate about scheduling or rejecting attempts to schedule

inspections without a reasonable explanation.

- Failure to provide a complete or accurate response relevant to an FDA inspection
- Refusal to permit entry to the establishment.
- Sending staff home or not operating the establishment during the scheduled inspection time.
- Establishing unreasonable preconditions that prevent a fulsome inspection.
- Delaying an inspection after it has started that interferes with a usual and customary inspection

FDA notes that a request to delay or reschedule is not a refusal of inspection, “when the delay or rescheduling is based on an unforeseen event or situation, such as a severe weather event that prevents the establishment from operating on the dates we proposed or scheduled.”

FDA is accepting comments on the guidance.

CIAA members with questions regarding the guidance may direct them to the Husch Blackwell team at CIAAGeneralCounsel@huschblackwell.com.



DATES TO REMEMBER

OCTOBER 31, 2022

Exporting countries that are designating U.S. importers for calendar year 2023 must submit their designations to FAS by this date.

NOVEMBER 10, 2022

CIAA Member Meeting
9:30am – 11:30am
Saddle Brook Marriot
Saddle Brook, NJ

DECEMBER 20, 2022 (approximately)

FAS issues first notice of calendar year 2023 licenses to licensees.

DECEMBER 31, 2022

Last day for licensees to make entries to fulfill the requirement to use 85% of their calendar year 2022 license amount. Last day for which calendar year 2022 licenses are valid. or "only 7 remaining"!

JANUARY 15, 2023

Winter Fancy Food Show Reception
5:00 pm -- 7:30 pm
Gordon Biersch Restaurant
Las Vegas, NV

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