

Regulatory Alert: FDA Resumes FSVP Inspections; Inspections Becoming Increasingly Rigorous

FDA Inspections Have Started Up Again Following Government Shutdown; U.S. Food Imports Goes Six for Six with NAI Inspections

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The U.S. Food and Drug Administration (FDA) has resumed inspecting importers for Foreign Supplier Verification Program (FSVP) compliance following the government shutdown. FDA is expected to aggressively enforce the regulation again this year. Within days of the shutdown ending, a client of U.S. Food Imports LLC (USFI) was contacted for inspection.

Over the past several months, USFI has assisted five clients with inspections over the past several weeks using our FSMA Cloud® and FDA Cloud® software applications. All of our clients' inspections have resulted in No Action Indicated (NAI) classifications (the best outcome). We also have been inspected ourselves as we act as the FSVP importer for retailers.

It is USFI's experience that the FDA inspections are becoming increasingly rigorous, particularly in regard to review of the hazard analyses of foreign suppliers. It is critical that importers obtain and review the hazard analyses of foreign suppliers (or use a qualified individual to do so). The hazard analysis must contain an assessment of the severity and probability of hazards. Merely obtaining a HACCP table detailing hazards and controls or a flow chart is not sufficient if it does not contain an assessment of the severity and probability of the hazards.

U.S. Food Imports LLC provides foreign supplier verification services and other food import solutions. Our proprietary FSMA Cloud® and FDA Cloud® software ensures efficient FSVP compliance for you and your suppliers. Please contact Erik Lieberman at elieberman@usfoodimports.com or (202)765-1800 if you have questions or would like additional information.

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