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MEMORANDUM

From: Joseph A. Levitt
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Date: August 28, 2017

Re: **FSMA Update: FDA Begins FSVP Inspections**

FDA has started conducting inspections to assess compliance with its Foreign Supplier Verification Programs (FSVP) regulation. The initial FSVP compliance date was May 30, 2017, though FSVP importers may have later compliance dates for their various suppliers that are smaller sized businesses. Inspections started earlier this summer. This memorandum provides a brief overview of how these inspections are progressing based on the inspections we have learned about.

Responsibility for complying with FDA falls on the FSVP "importer" (as that term is defined in 21 C.F.R. § 1.500) for the food. The FSVP importer is identified at entry through declaration of its name, email address, and Dun & Bradstreet Data Universal Numbering System (DUNS) number. 1/ FDA is inspecting the FSVP importer who is identified at entry for a given line entry of food. Inspections are being conducted on-site at the FSVP importer's place of business (though note that FDA has the legal authority to request that records be sent to the agency for review).

The agency's current approach is to provide advance notice of the inspection to the party identified at entry as the FSVP importer. This notice typically is being provided by a phone call or email a few days before the inspection. This contact usually comes directly from the FDA investigator who will be conducting the inspection. However, we understand that in the future FSVP inspections will not be announced, as FDA is currently pre-announcing inspections only because the regulation is new.

The inspections typically are focusing on 1 to 3 particular line entries of food, which the FDA investigator usually also identifies in advance. As with Preventive Controls inspections, FDA appears to be taking an "educate while we regulate" approach. Nevertheless, some companies are receiving inspectional observations at the close of their inspections using an FSVP-specific document named a "Form FDA 483a." This is the FSVP equivalent to the Form FDA 483 that may be issued following a facility inspection. As with a standard Form 483, a written response to a Form 483a is due to FDA within 15 business days of its receipt.

Also, as with facility inspections, FDA will prepare an Establishment Inspection Report following the inspection. A copy will be sent to the importer once the inspection (including any regulatory action) is closed.

1/ *See* Hogan Lovells memorandum dated May 11, 2017, *Action Required: FSVP Implementation Triggers New Data Entry Requirements for All Imported FDA-Regulated Foods on May 30, 2017*; Hogan Lovells memorandum dated April 4, 2017, *FDA Guidance Affirms Use of DUNS Numbers to Identify FSVP Importer*.

All businesses that import foods into the U.S., whether their imports are finished products or ingredients (including those from affiliates, subsidiaries, and parent companies), should review their supplier verification programs to ensure that they are prepared for an FSVP inspection. FDA has plans to conduct a significant number of FSVP inspections this fiscal year and next. Therefore, if you import food into the U.S. it is likely you will be inspected in the near future. In the event that you are notified of an upcoming inspection, consider conducting a desk audit or mock inspection for the product(s) at issue as part of your preparation and to facilitate an efficient inspection. You also should carefully review the recordkeeping requirements under the FSVP rule so that you understand the rule's recordkeeping requirements and which records you may be required to produce during the inspection.

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Hogan Lovells has experience navigating companies through FSVP inspections and is available to help in the event you are notified of an inspection or receive a Form 483a following an inspection. Should you have any questions, please do not hesitate to contact us.