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MEMORANDUM

From: Joseph A. Levitt
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Re: **FDA Publishes List of FSVP Importers Under FSMA**

The Food and Drug Administration (FDA) recently posted a document on its website that lists all importers that have been identified at entry in connection with the Foreign Supplier Verification Programs (FSVP) regulation. 1/ As discussed below, this posting is a statutory requirement under the FDA Food Safety Modernization Act (FSMA). The list simply provides all of the FSVP importer names that have been declared at entry, which means that some companies are listed multiple times with slight variations in their name. We expect the list is too general to help most companies determine whether there are any entries for which they have been declared as the FSVP importer without permission. However, the list could be helpful to companies that have never knowingly been declared as an FSVP importer so they can become aware they were declared and therefore may be subject to an FSVP inspection.

As background, FDA has a statutory obligation to publish a list of FSVP importers under FSMA, which states:

> PUBLICATION OF LIST OF PARTICIPANTS. – The Secretary shall publish and maintain on the Internet Web site of the Food and Drug Administration a current list that includes the name of, location of, and other information deemed necessary by the Secretary about, importers participating under this section. 2/

Responsibility for FSVP compliance falls on the "importer" as defined in FSVP. 3/ The FSVP importer is identified for each line entry of food when electronic entry is filed with U.S. Customs and Border Protection (CBP). Importer identification includes the importer's name, email address, and

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1/ The link to the current list is available at: https://tinyurl.com/fsvplist.
2/ FSMA § 301(a); Federal Food, Drug, and Cosmetic Act § 805(g) (21 U.S.C. § 384a(g)).
3/ For purposes of FSVP, "importer" is defined as "the U.S. owner or consignee of an article of food that is being offered for import into the United States. If there is no U.S. owner or consignee of an article of food at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer under this subpart." 21 CFR § 1.500. The term "U.S. owner or consignee" means "the person in the United States who, at the time of U.S. entry, either owns the food, has purchased the food, or has agreed in writing to purchase the food." *Id.*

Unique Facility Identifier (UFI) recognized as acceptable by FDA. FDA has recognized Dun & Bradstreet Data Universal Numbering System (DUNS) numbers as the acceptable UFI. 4/

The list FDA recently published on its website includes the "Firm Legal Name" and state for each FSVP importer that has been declared at entry. 5/ Many companies have numerous listings on this document, each with a slightly different variation of the company name and/or different state identified. This likely is due to discrepancies that occur when their data is input by brokers at entry.

We expect that the list is too general to use as a mechanism to "police" whether a company is declared as the FSVP importer without their permission. The list does not enable a company that knowingly serves as an FSVP importer for some foods to distinguish between which listings identified them correctly and which entries were made without their permission, as the information is not posted on a line entry- or DUNS number-specific basis. The only definite conclusion that can be drawn from the data is whether a company has ever been declared as an FSVP importer.

However, reviewing this list could be helpful to companies that have never knowingly served as the FSVP importer so that they can check to see if they have been declared as such. Inclusion on the list would mean that they could be subject to an FDA FSVP inspection. If such companies are listed, this could signal that they have been declared as the FSVP importer without permission. FDA's website explains that "in the event a discrepancy is detected" the incident should be reported to FDA for further investigation and remedial action by emailing ORAFSVPImporter@fda.hhs.gov.

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We will continue to monitor FDA's implementation of FSMA. Should you have any questions, please do not hesitate to contact us.

4/ *See* Hogan Lovells memorandum dated April 4, 2017, *FDA Guidance Affirms Use of DUNS Numbers to Identify FSVP Importer*.

5/ FDA advises that the list will be updated on a quarterly basis.