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MEMORANDUM

From: Joseph A. Levitt
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Date: October 11, 2019

Re: **FSMA Update: FDA Issues Draft Guidance on Recall Plans Under the Preventive Controls for Human Food Rule**

The U.S. Food and Drug Administration ("FDA") recently released Chapter 14 of its Draft Guidance for Industry, "Hazard Analysis and Risk-Based Preventive Controls for Human Food" ("Draft Guidance"). 1/ Entitled "Recall Plans," the chapter explains how food facilities subject to the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Rule ("PCHF Rule") can establish and implement a written recall plan. This memorandum provides a brief overview of the Draft Guidance. Comments on the Draft Guidance should be submitted by February 4, 2020. 2/

Background

Facilities covered by the PCHF Rule are required to have a written recall plan if they have any foods with a "hazard requiring a preventive control," as determined based on their hazard analysis. 3/ The regulations require the recall plan to include procedures that describe the steps to be taken, and assign responsibility for taking those steps, for the following actions, as appropriate to the facility:

1. Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food;
2. Notify the public about any hazard presented by the food when appropriate to protect public health;
3. Conduct effectiveness checks to verify that the recall is carried out; and

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1/ Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food, Chapter 14: Recall Plans (October 2019), *available at* https://www.fda.gov/media/131287/download?utm_campaign=FSMA%20Update%3A%20FDA%20Releases%20New%20Chapter%20of%20PC%20Human%20Food%20Draft%20Guidance%20on%20Developing%20A%20Recall%20Plan&utm_medium=email&utm_source=Eloqua

2/ Docket No. FDA-2016-D-2343.

3/ 21 CFR § 117.139(a).

4. Appropriately dispose of recalled food—*e.g.,* through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food. 4/

Overview of FDA's Draft Guidance

The Draft Guidance addresses each of the four regulatory requirements and includes specific recommendations for how to achieve each. A brief summary follows:

1. **Notifying Direct Consignees:** FDA recommends that the recall communication should identify the food, explain the reason for the recall (e.g., health hazard), specify the depth of the recall, provide instructions for what consignees should do with respect to the recalled food, describe how recipients can communicate with the recalling firm, and include model recall letters.

2. **Notifying the Public:** FDA explains that a recall plan should include procedures detailing whether and how to issue a public notice for the recall. The Draft Guidance states: "A public warning is reserved for urgent situations where other means of preventing use of the recalled product appear inadequate."

3. **Conducting Effectiveness Checks:** FDA references its existing guidance entitled "Industry Guidance for Recalls: Information on Recalls of FDA Regulated Products" as a source of guidance for how to conduct an effectiveness check.

4. **Disposition of Recalled Food:** FDA recommends that the recall plan describe the options that will be considered regarding appropriately disposing of recalled food and the factors that will be used to determine the appropriate disposition of recalled food.

Additionally, the Draft Guidance explains that the procedures in the recall plan must assign responsibility for taking each of the above steps. Throughout, the Draft Guidance cross-references FDA's recall regulations in 21 CFR Part 7, Subpart C.

FDA also recommends that the recall plan include procedures for notifying FDA about a recall (i.e., notifying the appropriate FDA Recall Coordinator), including procedures for notifying FDA about a Reportable Food under the Reportable Food Registry. Finally, FDA provides a list of resources that can help companies prepare a recall plan and that also may be helpful during a recall, which FDA recommends should be included in the recall plan itself.

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Hogan Lovells is available to review recall plans to ensure compliance and recall readiness. Please contact us if we can be of assistance or with any questions.

4/ 21 CFR § 117.139.