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MEMORANDUM

From: Joseph A. Levitt
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Re: **FDA Issues Draft Guidance on Mandatory Food Recalls Under FSMA**

The Food and Drug Administration (FDA) recently issued a draft guidance document entitled "Questions and Answers Regarding Mandatory Food Recall." The draft guidance sets out the basic framework governing FDA's use of its mandatory recall authority, which was granted by Section 206 of the FDA Food Safety Modernization Act (FSMA) and is codified in Section 423 of the Federal Food, Drug, and Cosmetic Act (FFDCA). The draft guidance document largely parrots the legal framework governing use of the mandatory recall authority. FDA is requesting that comments be submitted by July 6, 2015 to ensure that they will be taken into consideration when the final guidance is prepared.

FDA's mandatory recall authority went into effect on January 4, 2011, when FSMA was enacted. The FFDCA now gives FDA the authority to order a responsible party to recall food 1/ when FDA determines that there is a reasonable probability that the article of food is adulterated, or misbranded due to the presence of undeclared allergens, and that the use of or exposure to the food will cause serious adverse health consequences or death to humans or animals (SAHCODHA).

FDA explains that when deciding whether to move forward with a mandatory food recall, it will evaluate "all applicable evidence," which may include:

- Observations made during inspections of the responsible party or other parties;
- Results from sample analyses;
- Epidemiological data;
- Reportable Food Registry data; and
- Consumer and trade complaints.

The statute sets out a specific process that FDA must follow in order to mandate a recall. Once FDA has determined that the criteria for a mandatory recall have been met, the agency must first provide the responsible party with an opportunity to voluntarily cease distribution and recall the article of food. Though not discussed in the draft guidance, in application the agency provides such notice through a letter entitled "Notification of Opportunity to Initiate a Voluntary Recall letter." 2/

1/ The mandatory recall authority applies to all food except infant formula, which is covered by a different statutory provision governing recalls.

2/ As discussed in FDA's recently-issued "Annual Report to Congress on the Use of Mandatory Recall Authority – 2014," FDA has issued such letters twice since FSMA was enacted. The

The statute further provides that, if the responsible party refuses to, or does not voluntarily, cease distribution or recall the food as requested by FDA, the agency can use its mandatory recall authority and order the responsible party to cease distribution. Additionally, the responsible party has the opportunity to request an informal hearing (to be held within 2 days) to contest the order and convince FDA that the product should not be recalled. Recall orders can only be issued by the FDA Commissioner, and that authority cannot be delegated.

Additionally, the FFDCA authorizes the collection of fees for failure to comply with a food recall order. The fees are assessed on the responsible party for a domestic facility or the importer. The fees are intended to cover food recall activities associated with the order, including technical assistance, follow-up effectiveness checks, and public notifications. The draft guidance explains that noncompliance triggering assessment of such fees may include the following: (1) not initiating a recall as ordered by FDA; (2) not conducting the recall in the manner specified by FDA in the recall order; or (3) not providing FDA with requested information regarding the recall, as ordered by FDA. Civil monetary penalties also can be assessed for failure to comply with a recall order. Such fees and penalties can be avoided if the company agrees to recall the product voluntarily prior to issuance of a mandatory recall order.

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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.

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recipients were USPlabs LLC, a dietary supplement manufacturer, and Kasel Associates Industries, Inc., a pet treat manufacturer.