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MEMORANDUM

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Date: May 2, 2019

Re: **FDA Issues Draft Guidance on Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C**

The United States Food and Drug Administration (FDA) recently issued Draft Guidance for Industry entitled "Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C" (the Draft Guidance). 1/ As FDA Associate Commissioner for Regulatory Affairs Melinda K. Plaisier explained, part of FDA's work is "keenly focused on guiding companies on steps needed to ready their facilities and staff for possible recall situations." The Draft Guidance is the latest step in the Agency's efforts over the past 18 months to proactively and systematically update the FDA recall process.

Plaiser points to several examples of recalls that took place in the past 12 months that demonstrate that the improvements FDA and industry have implemented can result in more timely information being available to consumers. Plaisier also states that the agency's work to improve recall timeliness will continue and that FDA encourages the use of new technologies that can identify and communicate recall events more quickly and efficiently.

The Draft Guidance has four sections: A) preparing to facilitate timely initiation of a voluntary recall, B) identifying and responding to potential problems with distributed product, C) initiating a voluntary recall, and D) FDA's role in initiating a voluntary recall in a timely manner. In terms of significance, Plaisier highlights three key recommendations – training, record keeping, and procedures.

Following is a summary of the FDA draft guidance document:

1/ 84 Fed. Reg. 17112-17113 (Apr. 24, 2019); Draft Guidance on Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C, available at: https://www.fda.gov/media/123664/download. *See also*, Press Announcement, Statement from FDA Associate Commissioner for Regulatory Affairs Melinda K. Plaisier, on agency's new steps to strengthen the process of initiating voluntary recalls, available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm636462.htm.

A. How should a firm in a product distribution chain prepare to facilitate timely initiation of a voluntary recall?

To be generally "recall ready," FDA recommends every company identify and train recall personnel, establish a recall communications plan, identify any reporting requirements that apply to the company's products (e.g., the Reportable Food Registry), use product coding that allows for identification of product data (i.e., lot, batch, or unit information), and maintain complete distribution records. With respect to recordkeeping, Associate Commissioner Plaiser stated: "Thorough and organized record-keeping is especially important as the agency continues its efforts to improve recalls through product traceability by tapping into modern approaches such as blockchain technology to further advance our mission of protecting public health."

The Draft Guidance further advises a firm to maintain written recall initiation procedures that assign responsibility and describe the steps to perform all actions related to initiating a recall, as appropriate to the specific products and business model of the firm or facility. These procedures should include actions such as (1) ceasing distribution, shipment or sales of affected product; (2) developing a recall strategy; (3) notifying direct consignees; and (4) when appropriate, notifying the public of the recall.

The Draft Guidance reminds human and animal food firms that 21 CFR Parts 117 and 507 (issued under the FDA Food Safety Modernization Act (FSMA)) require written recall plans for food with a hazard requiring a preventive control.

B. What should a firm do if there is an indication of a problem with a distributed product?

In addition to the requirements in 21 CFR Parts 117 and 507, FDA encourages all firms to implement procedures to help identify indicators that there may be a problem with a distributed product. For example, companies can look to product specification deviation reports, out-of-specification testing results, and consumer complaints. A firm's identification of a potential problem should trigger investigation and evaluation procedures that will lead to the decision of whether and how to initiate a voluntary recall.

The Draft Guidance encourages companies to consult with FDA recall coordinators at any point in the internal investigation process.

C. How should a firm initiate a voluntary recall?

A firm should initiate a voluntary recall by promptly sending recall communications to each affected direct account, and by issuing a press release or other public notice, if appropriate. FDA considers the date of a firm's first communication about a recall, either to its direct accounts or to the public, to constitute the date of initiation. The Draft Guidance reiterates the timing and completeness requirements of voluntary recall communications. It directs firms to FDA's previously issued procedural guidance regarding press releases and written recall notification letters. Although FDA will review the content of draft communications and suggest changes, the Draft Guidance says that firms do not need to delay initiating a recall pending FDA review of such documents. The Draft Guidance also reiterates a recalling firm's responsibility to ensure any consignees respond to the recall communication by initiating its own effectiveness checks. The Draft Guidance also notes that outside of any legal reporting requirements, firms should notify the agency of a recall involving a violative product.

D. How does FDA work with a recalling firm to initiate a voluntary recall in a timely manner?

FDA emphasizes the cooperative nature of its role in the voluntary recall process. For example, FDA can assist with determining whether an action is considered a recall under 21 CFR § 7.3(g), assist in developing the recall strategy and drafting communications, and monitor the destruction, reconditioning, or disposition of a recalled product.

The Draft Guidance also discusses criteria that would trigger an FDA-requested recall under 21 CFR § 7.45: (1) a product that has been distributed presents a risk of illness or injury or gross consumer deception; (2) the firm has not initiated a recall of the product; and (3) an agency action is necessary to protect the public health and welfare. Note that this provision is separate from FDA's mandatory recall authority under FSMA.

Public Comment

Comments can be submitted to docket FDA–2018–D–2074 and are requested on or before June 24, 2019.

Significance

This Draft Guidance is part of a series of actions FDA has taken to streamline and make more efficient the agency's voluntary recall process. Companies should take special note of the new provision under FSMA that requires every food company under the Preventive Controls regulations to have a written recall plan. Equally noteworthy is FDA's continued attention on having food companies self-identify the need for voluntary recalls through internal investigations and root cause analyses, as well as the need to have the internal training, recordkeeping, and procedures in place to utilize when needed. The bottom line message is: "This will happen to you, so be ready!"

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We will continue to monitor FDA guidance regarding voluntary recalls. Please contact us if you are interested in submitting comments to FDA's docket, or if you have any questions on this or any other matter in the meantime. We also would be happy to assist in developing recall procedures.