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MEMORANDUM

From: Joseph A. Levitt
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Date: November 9, 2017

Re: **FDA Issues Guidance on Co-Manufacturer Supplier Verification Under FSMA**

The U.S. Food and Drug Administration ("FDA") recently issued a guidance document entitled "Supply-Chain Program Requirements and Co-Manufacturer Supplier Approval and Verification for Human Food and Animal Food: Guidance for Industry." 1/ This guidance is directed toward participants in "co-manufacturing" agreements in which a brand owner arranges for a second party (the "co-manufacturer") to manufacture food on its behalf and, as explained below, will affect contracts between brand owners and co-manufacturers, and brand owners and suppliers.

Overview

FDA explains in the guidance that it plans to exercise enforcement discretion for the next two years, until November 6, 2019, with respect to certain supplier verification requirements in situations where a brand owner performs supplier verification activities on behalf of its co-manufacturer. This enforcement discretion is conditional on the supplier approval and verification activities being clearly divided between the brand owner and the co-manufacturer. FDA is taking this action because industry expressed concerns that compliance with the supplier verification regulations may not be possible for co-manufacturers under existing contractual agreements.

Importantly, this enforcement discretion is only temporary. FDA expects brand owners and their co-manufacturers to modify their contractual agreements over the next 2 years so that co-manufacturers will have access to sufficient information from the brand owner to fully comply with the supplier verification regulations by November 6, 2019. Accordingly, brand owners that engage in supplier verification on behalf of their co-manufacturers will need to review and potentially revise their contract manufacturing agreements. This also may require brand owners to modify their contracts with suppliers so that they have permission to share information received from the supplier with the co-manufacturer.

This guidance is final and effective immediately, though comments can be submitted on guidance at any time. 2/

1/ Available at: https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm583475.htm.

2/ FDA is implementing this guidance without prior public comment, as permitted by 21 CFR § 10.115(g)(2), because it determined that public participation is not feasible or appropriate. FDA

Background

Under the Preventive Controls for Human Food and Preventive Controls for Animal Food (collectively, "Preventive Controls") regulations, a supply-chain program is required when a receiving facility identifies a hazard requiring a preventive control that is controlled before an ingredient's receipt by the facility. Although the co-manufacturer is responsible for approving its suppliers when a supply-chain program is required, there is some flexibility in the rules that allows the co-manufacturer to rely on a brand owner's supplier verification activities.

Specifically, the supply-chain program provisions of the Preventive Controls regulations provide that an entity such as a brand owner can determine, conduct, or both determine and conduct appropriate supplier verification activities on behalf of an entity such as a co-manufacturer, provided that the co-manufacturer documents its review and assessment of the brand owner's applicable supplier verification documentation. 3/ Thus, when a co-manufacturer relies on a brand owner to handle supplier verification activities, the co-manufacturer will need detailed information from the brand owner in order to meet its own obligations under the supply-chain program regulations.

Industry raised concerns to FDA that the requirements of the supply-chain program would require revisions to contracts between brand owners and their suppliers to allow brand owners to share certain information (e.g., audits of suppliers) with co-manufacturers. Industry also explained that establishing new contracts would take a significant period of time, impeding their ability to meet compliance dates. If a contract prevents a co-manufacturer from being able to review a brand owner's documentation of their supplier verification activities, the co-manufacturer would need to conduct its own supplier verification activities independent of the work the brand owner has performed. This may not always be feasible or may be duplicative of work already performed.

Scope of Enforcement Discretion

In this Guidance, FDA announces that in order to provide time for contracts to be revised to allow co-manufacturers to review all necessary documentation from the brand owner, "under certain circumstances and on a temporary basis," FDA does not intend to take enforcement action against a receiving facility that is a co-manufacturer and that is not in compliance with certain supply-chain program requirements for food manufactured for the brand owner. Specifically, in certain circumstances explained further below, FDA does not intend to take enforcement action regarding:

- 21 CFR § 117.410(d) / 21 CFR § 507.110(d) (issues that must be considered in approving suppliers and determining the appropriate supplier verification activities and their frequency); and

- 21 CFR § 117.415(a)(3) / 21 CFR § 507.115(a)(3) (activities that may be performed by an entity other than the receiving facility, so long as the receiving facility reviews and assesses the entity's applicable documentation and documents that review and assessment).

FDA also does not intend to take enforcement action under the Foreign Supplier Verification Programs (FSVP) regulation against an importer who is relying on the "deemed compliance" provision for FSVP and whose supply-chain program under Preventive Controls is subject to enforcement discretion under this guidance.

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made this determination "because the guidance represents a less burdensome policy consistent with the public health."

3/ 21 CFR §§ 117.415(a)(3) and 507.115(a)(3).

FDA explains that this enforcement discretion will apply in the following two circumstances:

1. Supplier Approval

FDA does not intend to take enforcement action if:

(1) a brand owner conducts supplier approval activities,
(2) the co-manufacturer describes these activities in its food safety plan, and
(3) the co-manufacturer conducts any necessary supplier approval activities not conducted by the brand owner.

For example, FDA does not intend to take enforcement action when a brand owner (rather than the co-manufacturer) evaluates supplier performance as part of approving a supplier, the co-manufacturer's food safety plan states that the brand owner will consider supplier performance before a supplier is approved, and the co-manufacturer conducts any other necessary supplier approval activities (e.g., hazard analysis of the food).

FDA emphasizes that under the regulations the co-manufacturer is always responsible for following written procedures for receiving raw materials and other ingredients, and documenting use of the procedures. 4/

2. Supplier Verification

FDA does not intend to take enforcement action if:

(1) a brand owner determines and/or conducts supplier verification activities for its co-manufacturer,
(2) the co-manufacturer describes these activities in its food safety plan, and
(3) the co-manufacturer conducts any necessary supplier verification activities not conducted by the brand owner.

For example, FDA does not intend to take enforcement action when an audit is determined to be the appropriate supplier verification activity but a co-manufacturer does not independently obtain a supplier audit or review the conclusions of a supplier audit obtained and reviewed by the brand owner, the co-manufacturer's food safety plan states that the brand owner will obtain and review audits of the supplier, and the co-manufacturer conducts any other necessary supplier verification activities (e.g., sampling and testing of the raw material or other ingredient).

Impacts for Food Companies

In the short term, co-manufacturers that want to take advantage of the enforcement discretion may need to revise their food safety plans to address situations where the brand owner is conducting supplier verification and approval activities on their behalf. Co-manufacturers also need to ensure they approve suppliers, have written procedures for receiving raw materials and other ingredients, and document use of those procedures.

In the longer term, every company involved in contract manufacturing should review their supplier verification programs and related contractual agreements in light of this guidance to ensure they have the ability to comply with the supplier-chain program requirements in the Preventive Controls rules. Before November 6, 2019, brand owners and their co-manufacturers may need to modify their contracts to address supplier verification responsibilities and information sharing. Both

4/ 21 CFR §§ 117.420 and 507.120.

agreements between brand owners/co-manufacturers and brand owners/suppliers may be affected. For example, brand owners may need to revise their agreements with suppliers so that they have permission to share information such as audit reports with their co-manufacturer.

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Should you have any questions or require assistance assessing the impact of this guidance for your co-manufacturing relationships or revising your contracts, please do not hesitate to contact us.