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MEMORANDUM

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Re: **FSMA Update: FDA Announces Continuation of Enforcement Discretion for Co-Manufacturer Supplier Verification**

On November 6, 2019, the Food and Drug Administration (FDA) announced in a Constituent Update that it will continue to exercise enforcement discretion with respect to certain supply-chain program requirements applicable to contract manufacturers ("co-manufacturers). 1/ The agency is taking this action to address situations where brand owners perform certain supply-chain program requirements on behalf of their co-manufacturers. This action extends the enforcement discretion FDA announced in November 2017, which was due to expire on November 6, 2019. Notably, FDA has not yet announced the length of time for this extension of the enforcement discretion, but plans to do so in a forthcoming *Federal Register* notice. This memorandum provides a background on this issue and explains FDA's recent announcement.

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. A co-manufacturer is considered a "receiving facility" under the rule. Although the co-manufacturer is responsible for approving its suppliers when a supply-chain program is required, there is some flexibility in the rule that allows the co-manufacturer to rely on a brand owner's supply-chain program activities.

Specifically, the supply-chain program provisions in the Preventive Controls regulations provide that another 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. 2/ Thus, when a co-manufacturer relies on a brand owner to handle supplier verification activities, the co-manufacturer will need detailed information from the

1/ Available at https://www.fda.gov/food/cfsan-constituent-updates/fda-continues-enforcement-discretion-policy-relevant-certain-co-manufacturers-under-fsma.
2/ 21 CFR §§ 117.415(a)(3) and 507.115(a)(3).

brand owner in order to meet its own obligations under the supply-chain program regulations. Industry has expressed concerns to FDA that these requirements may not be feasible.

FDA's 2017 Exercise of Enforcement Discretion

In November 2017, FDA issued Guidance explaining it would exercise enforcement discretion until November 6, 2019, for compliance with certain supply-chain program requirements related to these supplier approval and verification requirements. 3/ FDA decided to exercise enforcement discretion after hearing from industry that existing contracts among suppliers, co-manufacturers, and brand owners could hinder co-manufacturers' compliance with the requirements. In particular, co-manufacturers sometimes have no contractual relationship to suppliers, and as a result suppliers may not be willing to provide commercially sensitive information about their programs and practices to co-manufacturers. Brand owners typically are barred in their contracts with suppliers from sharing the information they receive from suppliers with third-parties, such as their co-manufacturers. Accordingly, the agency limited the enforcement discretion to two years to provide time for contracts to be revised and to allow co-manufacturers to review all necessary documentation from the brand owner.

The enforcement discretion applies to discrete supplier approval and verification activities under the rules:

- 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).

The enforcement discretion also extends to Foreign Supplier Verification Programs (FSVP) importers who are relying on the "deemed compliance provision" (21 CFR § 1.502(c)(3)) but whose supply-chain program is subject to this enforcement discretion regarding the provisions above.

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

3/ *Supply-Chain Program Requirements and Co-Manufacturer Supplier Approval and Verification for Human Food and Animal Food: Guidance for Industry* (Nov. 2017), available at https://www.fda.gov/media/108732/download. *See also* HL Memo - FDA Issues Guidance on Co-Manufacturer Supplier Verification Under FSMA (Nov. 9, 2017).

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).

FDA's Announcement of Continued Enforcement Discretion

FDA explains in the Constituent Update that since its original announcement, the agency has learned of additional challenges industry faces in complying with the supply-chain requirements. Comments submitted to FDA in support of an extension of enforcement discretion informed FDA that industry had faced difficulties revising contracts to allow brand owners to share supplier information with co-manufacturers, and that the rule presented additional challenges that could not be resolved just through contract revisions. For example, industry comments highlighted the resource burdens on both brand owners and co-manufacturers that would occur if verification needs to take place on the co-manufacturer level. Comments also expressed concern that entities would be required to hire additional personnel or redirect current personnel away from more substantive supply-chain work in order to facilitate compliance, but that these efforts would not add value for food safety.

In response to these comments, the agency announced that it plans to continue to work with stakeholders to better understand these challenges and identify solutions to overcome these obstacles. In the meantime, the agency will continue to exercise enforcement discretion. However, the agency has not yet announced how long it will continue this policy. The agency plans to announce the extension in a forthcoming *Federal Register* notice.

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Should you have any questions or require assistance assessing the impact of the enforcement discretion, please do not hesitate to contact us.

4/ 21 CFR §§ 117.420 and 507.120.