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Supply-Chain Program Requirements and Co-Manufacturer Supplier Approval and Verification for Human Food and Animal Food: Guidance for Industry

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Supply-Chain Program Requirements and Co-Manufacturer Supplier Approval and Verification for Human Food and Animal Food: Guidance for Industry¹

This guidance represents the current thinking of the Food and Drug Administration (FDA, the Agency, or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

This guidance is intended for persons who participate in certain “co-manufacturing” agreements in the production of human or animal food. By “co-manufacturing,” we mean a contractual arrangement whereby one party (the brand owner) arranges for a second party (the co-manufacturer) to manufacture/process human or animal food on behalf of the first party.

FDA has established requirements for a supply-chain program for raw materials and other ingredients for which a receiving facility has identified a hazard requiring a supply-chain-applied control in two regulations. The first regulation, which we established in 21 CFR part 117, is entitled “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food” (“part 117”). The second regulation, which we established in 21 CFR part 507, is entitled “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals” (“part 507”). Also, in our regulation entitled “Foreign Supplier Verification Programs for Importers of Food for Humans and Animals” (FSVP regulation; established in 21 CFR part 1, subpart L) we established that an importer that is a receiving facility is deemed to be in compliance with most of the requirements of the FSVP regulation for a food it imports, as long as the importer is in compliance with the supply-chain program requirements of part 117 or part 507 rule for that food. When an importer that is a receiving facility is in compliance with the supply-chain program requirements, the only

¹ This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition in cooperation with the Center for Veterinary Medicine and Office of Regulatory Affairs at the U.S. Food and Drug Administration.

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requirement of the FSVP regulation that applies is the requirement for importer identification at entry (21 CFR 1.509). Current industry co-manufacturing arrangements may include a supply-chain program established and implemented by the brand owner, the co-manufacturer, or both. This guidance advises such persons of specific circumstances in which FDA does not intend to take enforcement action regarding a co-manufacturer's compliance with the supply-chain program requirements.

Not all co-manufacturers are required to have supply-chain programs. If there are no hazards requiring supply-chain-applied controls in the raw materials and other ingredients used by a co-manufacturer, then the co-manufacturer does not need a supply-chain program, and this guidance is not applicable. This guidance is applicable when the brand owner approves and specifies to the co-manufacturer which suppliers must be used and there is a hazard that requires a supply-chain-applied control. Note, the brand owner is not considered the supplier of the co-manufacturer under the regulations if the brand owner does not manufacture/process the food, raise the animal, or grow the food that is provided to the co-manufacturer.

We are issuing this guidance consistent with our good guidance practices (GGP) regulation (21 CFR 10.115). This guidance is immediately effective because FDA has determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. Background

This guidance concerns three regulations that we have established in Title 21 of the Code of Federal Regulations (21 CFR) as part of our implementation of the FDA Food Safety Modernization Act (FSMA; Pub. L. 111–353).² These three regulations are part 117 (published in the *Federal Register* on September 17, 2015, 80 FR 55907), part 507 (published in the *Federal Register* on September 17, 2015, 80 FR 51670), and the FSVP regulation (published in the *Federal Register* of November 27, 2015, 80 FR 74226). Subparts A, B, and F of part 117 include current good manufacturing practice (CGMP) requirements for manufacturing, packing, or holding human food. Subparts A, C, D, E, F, and G of part 117 include requirements for domestic and foreign facilities that are required to register under section 415 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350d) to conduct a hazard analysis and implement risk-based preventive controls for human food (the human food preventive controls requirements). Subpart G of part 117 establishes requirements for a supply-chain program for those raw materials and other ingredients for which a receiving facility has identified a hazard requiring a supply-chain-applied control.

² For more information on the Agency's implementation of FSMA, see <http://www.fda.gov/fsma>.

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Part 117 defines a “receiving facility” as a facility that is subject to the human food preventive controls requirements and that manufactures/processes a raw material or other ingredient that it receives from a supplier. Part 117 defines a “supplier” as the establishment that manufactures/processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature. Part 117 defines a “supply-chain-applied control” as a preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt.

For domestic and foreign facilities that are required to register, subparts A, B, and F of part 507 include CGMP requirements and subparts A, C, D, E, and F of part 507 include requirements to conduct a hazard analysis and implement risk-based preventive controls for animal food (the animal food preventive controls requirements). Subpart E of part 507 establishes requirements for a supply-chain program for raw materials and other ingredients for which a receiving facility has identified a hazard requiring a supply-chain-applied control. The provisions and applicability of part 507, subpart E, and the definitions established in part 507 for “receiving facility,” “supplier,” and “supply-chain-applied control” are analogous to those of part 117.

Under the FSVP regulation, importers are required to develop, maintain, and follow a foreign supplier verification program that, among other things, provides adequate assurance that foreign suppliers are producing food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 of the FD&C Act (which authorized the supply-chain programs in 21 CFR parts 117 and 507) (see 21 CFR 1.502(a)). An importer that is a receiving facility subject to section 418 of the FD&C Act is deemed to be in compliance with the requirements of the FSVP regulation, except the importer identification requirements in 21 CFR 1.509, if the importer has established and implemented a risk-based supply-chain program in compliance with 21 CFR part 117, subpart G or part 507, subpart E (21 CFR 1.502(c)(3)).

Under the definition of “receiving facility” established in parts 117 and 507, co-manufacturers that are subject to the human food or the animal food preventive controls requirements and that manufacture/process a raw material or other ingredient received from a supplier are receiving facilities. Co-manufacturers that are receiving facilities that have identified a hazard in a raw material or ingredient requiring a supply-chain-applied control are required to approve their suppliers for those raw materials or other ingredients. However, the supply-chain provisions permit an entity other than the receiving facility (e.g., permit the brand owner) to determine, conduct, or both determine and conduct, appropriate supplier verification activities, provided that the receiving facility documents its review and assessment of the other entity’s applicable documentation. (See 21 CFR 117.415(a)(3) and 507.115(a)(3).) Specifically, the rules allow for a co-manufacturer to base its verification of suppliers on review of adequate documentation of the brand owner’s supplier verification activities.

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III. Discussion

Industry has expressed concerns 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, and that establishing new contracts would take a significant period of time, impeding their ability to meet compliance dates (Ref. 1).

As noted in section II, the supply-chain program provisions permit a co-manufacturer to review and assess documentation of a brand owner's determination, conduct, or both determination and conduct, of appropriate supplier verification activities, provided that the co-manufacturer documents its review and assessment of the brand owner's applicable documentation. (See 21 CFR 117.415(a)(3) and 507.115(a)(3).) If a contract prevents a co-manufacturer from being able to review a brand owner's documentation of supplier verification activities, the co-manufacturer would not be able to verify suppliers based on its review of that documentation. Consequently, the co-manufacturer would need to conduct supplier verification activities (e.g., on-site audits) that might otherwise not be required.

To provide time for contracts to be revised to allow co-manufacturers to review all necessary documentation from the brand owner, FDA is announcing that, under certain circumstances and on a temporary basis, we do 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, we do not intend to take enforcement action regarding 21 CFR 117.410(d) and 117.415(a)(3) or 21 CFR 507.110(d) and 507.115(a)(3) in the circumstances described below. Furthermore, we do not intend to take enforcement action under the FSVP regulation against an importer who is relying on 21 CFR 1.502(c)(3) but whose supply-chain program is subject to enforcement discretion regarding 21 CFR 117.410(d) and 117.415(a)(3) or 21 CFR 507.110(d) and 507.115(a)(3) in the circumstances described below.

Supplier Approval

FDA does not intend to take enforcement action under the following circumstances: (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). The co-manufacturer is always responsible for following written procedures for receiving raw materials and other ingredients, and documenting use of the procedures (21 CFR §§ 117.420 and 507.120).

Supplier Verification

FDA does not intend to take enforcement action under the following circumstances: (1) a brand owner determines and/or conducts supplier verification activities for its co-manufacturer, (2) the

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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).

We do not intend to take enforcement action regarding the affected provisions until November 6, 2019.

Co-manufacturers to whom this policy applies still must comply with the importer identification requirements in 21 CFR 1.509, if they are also FSVP importers. Under 21 CFR 1.509(a), for each line entry of food product offered for importation into the United States, the importer must provide its name, electronic mail address, and unique facility identifier recognized as acceptable by FDA electronically when filing entry with U.S. Customs and Border Protection. FDA has recognized the Dun & Bradstreet Data Universal Numbering System (DUNS) number as an acceptable unique facility identifier for the FSVP rule. When a food product under FDA oversight is offered for entry into the United States, the U.S. Customs and Border Protection (CBP) Automated Commercial Environment (ACE) system will prompt the filer to transmit an "FSV" entity role code indicating the entry line is subject to the FSVP regulation and currently subject to FSVP enforcement. For more information on importer identification, consult "Guidance for Industry: Compliance with Providing an Acceptable Unique Facility Identifier for the Foreign Supplier Verification Programs Regulation," available at <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm556661.htm>.

IV. References

The following references are on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the Web site addresses, as of the date of this document, but Web sites are subject to change over time.

1. Letter from Grocery Manufacturers Association to Dr. Stephen Ostroff, Acting Commissioner of Food and Drugs, February 7, 2017.