4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 117, and 507

[Docket No. FDA-2017-D-5996]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a guidance for industry entitled "Supply-Chain Program Requirements and Co-Manufacturer Supplier Approval and Verification for Human Food and Animal Food." The guidance announces that 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 in the "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" and "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals" regulations (preventive controls regulations) for food manufactured for the brand owner, under certain circumstances, until November 6, 2019. Furthermore, we do not intend to take enforcement action under the Foreign Supplier Verification Programs (FSVP) regulation against an importer whose supply-chain program is subject to enforcement discretion under the preventive controls regulations until November 6, 2019.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions*: All submissions received must include the Docket No. FDA-2017-D-5996 for "Supply-Chain Program Requirements and Co-Manufacturer Supplier Approval and Verification for Human Food and Animal Food." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the

body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

*Docket*: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: *For questions relating to the guidance as it applies to human food*: Jenny Scott, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2166. *For questions relating to the guidance as it applies to animal food*: Jeanette Murphy, Center for Veterinary Medicine (HFV-200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-6246.

SUPPLEMENTARY INFORMATION:

## I. Background

We are announcing the availability of a guidance for industry entitled "Supply-Chain Program Requirements and Co-Manufacturer Supplier Approval and Verification for Human Food and Animal Food: Guidance for Industry." We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). We made this determination because the guidance represents a less burdensome policy consistent with the public health. Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA's GGP regulation. This guidance is not subject to Executive Order 12866.

The 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. The 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). (For more information on the Agency's implementation of FSMA, see https://www.fda.gov/fsma.) These three regulations are part 117 (21 CFR part 117) (published in the *Federal Register* on September 17, 2015, 80 FR 55908), part 507 (21 CFR part 507) (published in the *Federal Register* on September 17, 2015, 80 FR 56170), and the FSVP regulation (published in the *Federal Register* of November 27, 2015, 80 FR 74226). Subpart G of part 117 and subpart E of part 507 establish 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.

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 Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350g) (which authorized the supply-chain programs in parts 117 and 507) (see § 1.502(a) (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 part 117, subpart G or part 507, subpart E (§ 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 §§ 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.

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). 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 (§§ 117.410(d) and 117.415(a)(3) or §§ 507.110(d) and 507.115(a)(3)) for food manufactured for the brand owner until November 6, 2019. Furthermore, we do not intend to take enforcement action under the FSVP regulation against an importer who is relying on § 1.502(c)(3) but whose supply-chain program is subject to enforcement discretion regarding §§ 117.410(d) and 117.415(a)(3) or §§ 507.110(d) and 507.115(a)(3).

The guidance represents the current thinking of FDA 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 statues and regulations.

## II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in part 117 have been approved under OMB control number 0910-0751. The collections of information in part 507 have been approved under OMB control number 0910-0789.

## III. Electronic Access

Persons with access to the internet may obtain the document at https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/default.htm, https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/default.htm, or https://www.regulations.gov. Use the FDA websites listed in the previous sentence to find the most current version of the guidance.

## IV. Reference

The following reference is on display in the Dockets Management Staff (see ADDRESSES) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at https://www.regulations.gov.

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

Dated: October 31, 2017.
Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.
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