FSMA also includes provisions requiring certain food facilities to implement preventive controls to, among other things, provide assurances that hazards identified in a hazard analysis will be significantly minimized or prevented. FDA's final rules on current good manufacturing practice, hazard analysis, and risk-based preventive controls for human food (80 FR 55908, September 17, 2015) and for animal food (80 FR 56170, September 17, 2015) include provisions requiring receiving facilities to conduct a hazard analysis and to establish and implement supply-chain programs for domestic and imported raw materials and other ingredients for which the facility has identified a hazard requiring a supply-chain applied control.

The preventive controls requirements, including the supply-chain program provisions, do not apply to facilities that are solely engaged in the storage of non-produce RACs (including grain RACs) intended for further distribution or processing. However, the FSVP regulation applies to all importers of non-produce RACs, including importers that are solely engaged in the storage of these RACs intended for further processing.

The guidance describes FDA's current thinking on the application of the FSVP regulation to importers of grain RACs. To better align the FSVP regulation with the exemption from preventive controls requirements for facilities solely engaged in the storage of non-produce RACs, and because of the nature of the hazards associated with grain RACs and how they are generally addressed in the distribution chain, we intend to exercise enforcement discretion for importers of grain RACs that are solely engaged in the storage of grain intended for further distribution or processing with respect to the FSVP regulation. This intent to exercise enforcement discretion with respect to FSVP also applies to grain importers that do not take physical possession of the grain they import but instead arrange for the delivery of the grain to others for storage, packing or manufacturing/processing.

## 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 21 CFR part 1, subpart L have been approved under OMB control number 0910–0752.

## III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/FoodGuidances* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: January 18, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–01298 Filed 1–24–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 1

**[Docket No. FDA–2017–D–5225]**

## Foreign Supplier Verification Programs for Importers of Food for Humans and Animals; Draft 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 draft guidance for industry entitled ''Foreign Supplier Verification Programs for Importers of Food for Humans and Animals.'' The draft guidance, once finalized, will provide our thinking on how importers of human or animal food can comply with the regulation on foreign supplier verification programs (FSVPs) issued on November 27, 2015.

**DATES:** Submit either electronic or written comments on the draft guidance by May 25, 2018 to ensure that the Agency considers your comments on this draft guidance before it completes a final version of the guidance,

**ADDRESSES:** You may submit comments on any guidance 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–5225 for ''Foreign Supplier Verification Programs for Importers of Food for Humans and Animals: Guidance for Industry.'' 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 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Outreach and Information Center (HFS–009), Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Mischelle B. Ledet, Office of Compliance (HFS–600), Center for Food Safety and Applied Nutrition, 5001 Campus Dr., College Park, MD 20740, 240–701–5986.

**SUPPLEMENTARY INFORMATION:**

## I. Background

In the **Federal Register** of November 27, 2015 (80 FR 74226), we issued a final rule adopting a regulation on foreign supplier verification programs (FSVPs) for importers of food for humans and animals (FSVP final rule). The FSVP final rule implements section 301 of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353), which enables the Agency to better protect public health by helping to ensure the safety and security of the food supply.

Section 301 of FSMA added section 805 to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384a) to require persons who import food into the United States to perform risk-based foreign supplier verification activities. In addition to directing FDA to issue regulations on the content of FSVPs, section 805 directs FDA to issue guidance to assist importers in developing FSVPs.

In accordance with section 805 of the FD&C Act, we are announcing the availability of a draft guidance for industry entitled ''Foreign Supplier Verification Programs for Importers of Food for Humans and Animals.'' The draft guidance, once finalized, will provide our thinking on how to comply with the FSVP regulation, including, but not limited to, requirements to analyze the hazards in food, evaluate a potential foreign supplier's performance and the risk posed by a food, and determine and conduct appropriate foreign supplier verification activities. The draft guidance also addresses how importers can meet the modified FSVP requirements for importers of dietary supplements, very small importers, importers of food from certain small foreign suppliers, and importers of food from countries whose food safety systems we have officially recognized as comparable or determined to be equivalent to that of the United States.

The draft guidance reflects interpretations regarding two matters addressed in the preamble to the FSVP final rule that differ from the interpretations expressed there. First, the draft guidance reflects an interpretation that is different from our statement in the preamble to the FSVP final rule that waxing and cooling raw agricultural commodities, when done by a packing operation for purposes of storage or transport, may be considered a packing activity (see 80 FR 74226 at 74236 (Comment/Response 14)). Instead, the draft guidance states that such activities may be packing activities and/or holding activities, depending on the circumstances. This change reflects our revised thinking regarding the classification of waxing, which we now consider may be incidental to holding (not packing) under certain circumstances (see ''Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities: Draft Guidance for Industry'' (81 FR 58421, August 25, 2016) available at: *https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM517575.pdf*). Second, the draft guidance reflects an interpretation that differs from our statement in the preamble to the FSVP final rule that there may be circumstances in which hazards that may be intentionally introduced by acts of terrorism may present a known or reasonably foreseeable hazard, such that importers may need to address these hazards as part of their supplier verification activities (see 80 FR 74226 at 74281 (Comment/Response 174)). That statement assumed that importers would consider such hazards in their hazard analyses. In the draft guidance, we clarify that importers are not required under the FSVP regulation to consider in their hazard analysis hazards that are intentionally introduced to cause wide scale public health harm. Instead, importers should consider warning letters or other enforcement action taken by FDA against foreign suppliers for violation of FDA's regulation on intentional adulteration (in 21 CFR part 121) as part of their evaluation of potential suppliers under 21 CFR 1.505 in the FSVP regulation. Our prior statements were incorrect and we hereby withdraw them. We further explain our thinking on these matters in the FSVP draft guidance.

## II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 may use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This draft guidance is not subject to Executive Order 12866.

## III. Paperwork Reduction Act of 1995

This draft 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 21 CFR part 1, subpart L, have been approved under OMB control number 0910–0752.

## IV. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/FoodGuidances* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the draft guidance.

Dated: January 18, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–01297 Filed 1–24–18; 8:45 am]

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