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–2011–N–0143 for ''What You Need to Know About the FDA Regulation: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals—Small Entity Compliance Guide.'' 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)).

See the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

FOR FURTHER INFORMATION CONTACT: Sharon Mayl, Office of Foods and Veterinary Medicine, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4719.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 27, 2015 (80 FR 74225), we issued a final rule entitled ''Foreign Supplier Verification Programs for Importers of Food for Humans and Animals'' (the final rule) that requires importers to perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that meets applicable U.S. safety standards. The final rule, which is codified at 21 CFR part 1, subpart L, became effective January 26, 2016, but has compliance dates starting May 30, 2017.

We examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612) and determined that the final rule will have a significant economic impact on a substantial number of small entities. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121, as amended by Pub. L. 110–28), we are making available the SECG to reduce the burden of determining how to comply by further explaining and clarifying the actions that a small entity must take to comply with the rule.

We are issuing the SECG consistent with our good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG 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 statutes and regulations. This guidance is not subject to Executive Order 12866.

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 SECG 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 19, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–01300 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–6592]

Application of the Foreign Supplier Verification Program Regulation to Importers of Grain Raw Agricultural Commodities: Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of a guidance for industry entitled ''Application of the Foreign Supplier Verification Program Regulation to Importers of Grain Raw Agricultural Commodities: Guidance for Industry.'' This guidance is intended to explain our intent to exercise enforcement discretion for importers of grain raw agricultural commodities (RACs) that are solely engaged in the storage of grain intended for further distribution or processing and 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.

DATES: The announcement of the guidance is published in the **Federal Register** on January 25, 2018.

ADDRESSES: You may submit either electronic or written comments on FDA 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–6592 for ''Application of the Foreign Supplier Verification Program Regulation to Importers of Grain Raw Agricultural Commodities: 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 guidance to Office of Food Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS–300), 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: Sharon Mayl, Office of Foods and Veterinary Medicine, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4719.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled ''Application of the Foreign Supplier Verification Program Regulation to Importers of Grain Raw Agricultural Commodities: Guidance for Industry.'' We are issuing the guidance consistent with our good guidance practices regulation § 10.115 (21 CFR 10.115). In accordance with § 10.115(g)(2), we are implementing the guidance immediately because we have determined that prior public participation is not feasible or appropriate. We made this determination because this guidance document provides information pertaining to regulations with which many importers were required to comply as of May 30, 2017, and it sets out compliance policy that reduces regulatory burdens for importers of certain raw agricultural commodities. Although the guidance document is immediately in effect, we invite comments at any time in accordance with the Agency's good guidance practices (§ 10.115(g)(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 alternate approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) enables FDA to better protect public health by helping to ensure the safety and security of the food supply. It amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to add, among other food safety requirements, provisions requiring the verification of the safety of food imported from foreign suppliers of that food.

Section 805(c) of the FD&C Act (21 U.S.C. 384a(c)) directs FDA to issue regulations on the content of Foreign Supplier Verification Programs (FSVPs). We issued the FSVP final rule on November 27, 2015 (80 FR 74225). The FSVP regulation requires food importers to develop, maintain, and follow an FSVP that provides adequate assurances that the foreign supplier uses processes and procedures that provide the same level of public health protection as those required under the preventive controls and produce safety provisions of FSMA (if applicable) and regulations implementing those provisions, as well as assurances that the imported food is not adulterated and that human food is not misbranded with respect to allergen labeling.

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'').

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- 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