Commission's Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or e-mail at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. E-mail the Public Reference Room at *public.referenceroom@ferc.gov*.

By direction of the Commission. Commissioner LaFleur is concurring with a separate statement attached.

Issued: January 18, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

Attachment

LaFLEUR, Commissioner *concurring:*

In today's order, the Commission proposes to approve the supply chain risk management standards filed by the North American Electric Reliability Corporation (NERC), and direct certain modifications to those standards. I write separately to explain my vote in support of today's order, given my dissent on the Commission order that directed the development of these standards.[1]

As I stated in my dissent, I shared the Commission's concern about supply chain threats and supported continued Commission attention to those threats. Indeed, I remain concerned that the supply chain is a significant cyber vulnerability for the bulk power system. However, I believed that the Commission was proceeding too quickly to require a supply chain standard, without having sufficiently worked with NERC, industry, and other stakeholders on how to design an effective, auditable, and enforceable standard. In my view, the directive that resulted was insufficiently developed and created a risk that needed protections against supply threats would be delayed, due in large part to the nature of the NERC standards process.

Given the limited guidance and timeline provided by the Commission in Order No. 829, the proposed standards are, unsurprisingly, quite general, focusing primarily ''on the processes Responsible Entities implement to consider and address cyber security risks from vendor products or services during BES Cyber System planning and procurement, not on the outcome of those processes . . .'' [2] The proposed standards would provide significant flexibility to registered entities to determine how best to comply with their requirements. In my view, that flexibility presents both potential risks and benefits. It could allow effective, adaptable approaches to flourish, or allow compliance plans that meet the letter of the standards but do not effectively address supply chain threats. I hope that we will see more of the former, but I believe the Commission, NERC, and the Regional Entities should closely monitor implementation if the standards are ultimately approved.

In voting for today's order, I recognize that the choice before the Commission today is not the same as it was in July 2016. I acknowledge that a significant amount of time and effort have been committed to the development of these standards in response to a duly voted Commission order. Most importantly, I agree that they are an improvement over the *status quo.* I do not believe that remanding these standards or the larger supply chain issue to the NERC standards process would be a prudent step at this point. Rather, I believe the better course of action at this time is to move forward with these standards and, assuming the Commission ultimately proceeds to Final Rule, improve them over time as needed.

In that regard, I believe the Commission is appropriately proposing to direct a modification to the proposed standards to address an identified reliability gap regarding Electronic Access Control and Monitoring Systems. I also support the proposal to require NERC to include Physical Access Controls and Protected Cyber Assets within its ongoing assessment of the supply chain risks posed by low-impact Bulk Electric System Cyber Systems, which will help the Commission and NERC determine whether further revisions to the standards are needed.

More so than with most standards, I believe that whether these standards are effective will only reveal itself over time as we gain additional experience with them. I am therefore particularly interested in feedback from commenters on how the Commission, NERC, and industry should assess these standards, including any reporting obligations that might be appropriate.[3] In addition, given the very general process-oriented nature of the standard, I also support the proposal to shorten the implementation date for the new standards. If ultimately adopted, the revised deadline will allow industry, NERC, and the Commission to put the standards in place sooner while continuing to evaluate how best to protect the bulk power system against supply chain threats.

For these reasons, I respectfully concur.

Cheryl A. LaFleur,

Commissioner.

[FR Doc. 2018–01247 Filed 1–24–18; 8:45 am]

BILLING CODE 6717–01–P

[1] *Revised Critical Infrastructure Protection Reliability Standards,* Order No. 829, 156 FERC ¶ 61,050 (2016) (LaFleur, Comm'r, *dissenting*).

[2] NERC Petition at 27.

[3] I note that NERC has also developed draft implementation guidance that provides additional detail regarding possible compliance approaches. As NERC and the Regional Entities gain additional experience with assessing compliance under these standards, updating this implementation guidance could be an effective approach for quickly disseminating best practices and lessons learned.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2011–N–0143]

Foreign Supplier Verification Programs for Importers of Food for Humans and Animals: What You Need To Know About the Food and Drug Administration Regulation; Small Entity Compliance Guide; 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 ''Foreign Supplier Verification Programs for Importers of Food for Humans and Animals: What You Need to Know About the FDA Regulation; Small Entity Compliance Guide.'' The small entity compliance guide (SECG) is intended to help small entities comply with the final rule entitled ''Foreign Supplier Verification Programs for Importers of Food for Humans and Animals.''

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 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–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.