4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA-2011-N-0179]

Prior Notice of Imported Food Questions and Answers (Edition 4); Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled "Prior Notice of Imported Food Questions and Answers; Draft Guidance for Industry (Edition 4)." The draft guidance adds three additional questions. One question relates to any effect systems recognition or equivalency determinations have on prior notice requirements. The other two questions relate to FDA's notice to a submitter of prior notice of an FDA refusal for inadequate prior notice or hold if the food article is from a foreign facility that is not registered, and address the timeframe for making requests for FDA review of such a refusal or hold. FDA is also making other technical and editorial changes.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that we consider your comment on this draft guidance before we begin work on the final version of the guidance.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-2011-N-0179 for "Prior Notice of Imported Food Questions and Answers; Draft Guidance for Industry (Edition 4)." 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, 240-402-7500.

- 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." FDA 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.govinfo.gov/content/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, 240-402-7500.

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 Division of Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, Element Building, 12420 Parklawn Dr., Rockville, MD 20852. 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: Chris Henderson, Office of Regulatory Affairs, Food and Drug Administration, Element Building, 12420 Parklawn Dr., Rockville, MD 20857 240-402-8186, Christopher.Henderson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry, entitled "Prior Notice of Imported Food Questions and Answers; Draft Guidance for Industry (Edition 4)." This draft revised guidance is being issued for public comment and has not yet been finalized. Until edition 4 is finalized, "Prior Notice of Imported Food Questions and Answers; Guidance for Industry (Edition 3)," updated most recently in 2016, remains in effect. We are issuing the draft guidance consistent with our 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 can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

FDA continues to believe that it is reasonable to maintain responses to questions concerning prior notice of imported food in a single document that is periodically updated in response to additional questions or regulatory or policy changes. As in the previous editions, the following indicators are used to help users identify revisions: (1) the guidance is identified as a revision of a previously issued document; (2) the revision date appears on the cover of the guidance; (3) the edition number of the guidance is included in its title; and (4) revised or added questions and answers are identified as such in the body of the guidance.

On November 7, 2008, we published a final rule in the *Federal Register* requiring submission to FDA of prior notice of food, including food for animals, that is imported or offered for import into the United States (73 FR 66294). The rule implements section 801(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 381(m)), which was added by section 307 of the Public Health Security and Bioterrorism Preparedness and Response

Act of 2002 (the Bioterrorism Act) (Pub. L. 107-188) and requires that FDA receive prior notice of food imported or offered for import into the United States.

On December 16, 2003, FDA issued a guidance entitled "Prior Notice of Imported Food Questions and Answers (Edition 1)." FDA issued a second and third edition on May 3, 2004, and June 16, 2016, respectively. This draft will be the fourth edition of this document. FDA is issuing this draft guidance entitled "Prior Notice of Imported Food Questions and Answers (Edition 4)" as a level 1 guidance.

The draft fourth edition guidance adds three additional questions. One question relates to any effect systems recognition or equivalency determinations have on prior notice requirements. The other two questions relate to FDA's notice of a refusal under 801(m)(1) of the FD&C Act (in accordance with § 1.283 (21 CFR 1.283)) for inadequate prior notice or a hold under 801(l) (in accordance with § 1.285 (21 CFR 1.285)) if the food article is from a foreign facility that is not registered, as well as address the timeframe for making requests for FDA review of such a refusal or hold. The draft guidance is intended to help clarify whether food imported from a country with which FDA has a Systems Recognition Arrangement or equivalence determination is exempted from prior notice requirements. The draft guidance also intends to clarify when FDA will provide notice of the refusal or hold to the relevant party, and when the 5-calendar-day clock to request a review of the refusal or hold begins. We are also making other technical amendments to the guidance due to the expanded capabilities of the U.S. Customs and Border Protection's Automate Broker Interface of the Automated Commercial Environment (ABI/ACE) system and FDA's 2017 technical amendments to the prior notice rule (82 FR 15627, March 20, 2017), such as replacing references to the Automated Commercial System (ACS) and successor system with the ABI/ACE system, removing references to requirements that certain prior notice submissions be submitted in FDA's Prior Notice Systems Interface (FDA PNSI), and updating outdated links and FDA contact information.

The draft fourth edition guidance clarifies that the existence of a Systems Recognition Arrangement with or an equivalence determination of a foreign country does not exempt imported foods from that country from FDA's prior notice requirements.

FDA's policy on and practice of communicating prior notice refusals and holds has changed over time. FDA previously stated that we intended to provide notice regarding refusals to carriers. Those carriers could then notify others, such as the entity that hired the carrier to transport the article of food, of a problem with the prior notice(see 73 FR 66294 at 66365). Subsequently, FDA's Guidance for Industry "Prior Notice of Imported Food Questions and Answers (Edition 3)" was published with the explanation that FDA will communicate the decision to examine articles of food to CBP.

The draft fourth edition clarifies that notification of these prior notice refusals and holds will be communicated to CBP and provided to the relevant party (i.e., the submitter of prior notice) upon arrival of the article. FDA is clarifying its policy because providing advanced notice of a refusal or hold to a submitter could create incentives for bad actors, who may attempt to reroute their entries for the purpose of evading FDA requirements and importing unsafe food.

The draft fourth edition also clarifies the 5-calendar-day clock to request a review of these refusals and holds. Under §§ 1.283(d) and 1.285(j), certain parties may, for the enumerated reasons, request reviews of the prior notice refusals and holds within 5 calendar days of the hold or refusal. The draft fourth edition clarifies that FDA considers the 5-calendar-day clock to begin when FDA provides notice of the refusal or hold to the submitter.

Additionally, in 2016, CBP issued a notice announcing that ABI/ACE would replace ACS as the sole electronic data interchange system authorized by CBP for the processing of electronic entries of FDA-regulated products (see 81 FR 30320, May 16, 2016). ABI/ACE became the successor system to ACS. In 2017, we amended 21 CFR subpart I to replace references to ACS and successor system with ABI/ACE (see 82 FR 15627). As part of this rulemaking, we eliminated some requirements for submitting prior notice due to the expanded

capabilities of ABI/ACE, such as the requirement to submit articles that have been refused under section 801(m)(1) of the FD&C Act or subpart I in FDA PNSI. Further, ABI/ACE can now accommodate entries it previously could not, such as articles of food arriving through international mail. Therefore, to reflect these changes that were implemented in the rulemaking and the expanded capabilities of ABI/ACE, we are replacing references in the guidance to ACS and successor system with ABI/ACE. In addition, we are providing clarification regarding how persons may submit prior notice for articles of food imported or offered for import by international mail.

This 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 "Prior Notice of Imported Food Questions and Answers (Edition 4)." 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR 1.278 to 1.282 have been approved under OMB control number 0910-0520.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at https://www.fda.gov/food/importing-food-products-united-states/prior-notice-imported-foods, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or

https://www.regulations.gov. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: September 7, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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