114164-01-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 3); 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 guidance for industry entitled "Prior Notice of Imported Food Questions and Answers (Edition 3): Guidance for Industry." The guidance provides updated information pertaining to prior notice of imported food under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Food Safety Modernization Act (FSMA) on January 4, 2011. The guidance is intended to help the food industry and others comply with prior notice requirements.

DATES: Submit either electronic or written comments on FDA guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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 (Edition 3): Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management 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 http://www.regulations.gov. Submit both copies to the Division of Dockets Management. 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: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Office of Regulatory Affairs, Office of Food and Feed Operations, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993. 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: Angel M. Suarez, Office of Regulatory Affairs, Office of Food and Feed Operations, Division of Food Defense Targeting, Food and Drug Administration, Element Bldg., HFC-180, 12420 Parklawn Dr., Rockville, MD 20857-20993, 866-521-2297.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Prior Notice of Imported Food Questions and Answers (Edition 3): Guidance for Industry." We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). 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 on the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

Since publication of edition two of the guidance, FDA has issued a final rule requiring the submission to FDA of prior notice of food, including animal feed, imported or offered for import into the United States (November 7, 2008, 73 FR 66294) and, in accordance with section 304 of FSMA, a final rule requiring the name of any country to which an article has been refused entry be reported in prior notices (May 30, 2013, 78 FR 32359). FDA is issuing a third edition of its prior notice guidance to address questions received since publication of the second edition,

clarify previous responses, update previous responses as appropriate to reflect the 2008 final rule, and include information about the new prior notice information requirement created by FSMA.

FDA issued the first and second editions of this guidance on December 16, 2003, and May 3, 2004, respectively. Both editions were issued as Level 1 guidance documents under 21 CFR 10.115. Consistent with FDA's good guidance practices regulations (21 CFR 10.115(g)(2), the Agency accepted comments, but implemented the documents immediately because it determined that prior public participation was not feasible or appropriate.

In the Federal Register of March 31, 2014 (79 FR 17947), we made available a draft guidance for industry entitled "Draft Guidance for Industry: Prior Notice of Imported Food Questions and Answers (Edition 3)" and gave interested parties an opportunity to submit comments by May 30, 2014, for us to consider before beginning work on the final version of the guidance. We carefully considered all comments received when preparing the final guidance. No substantive changes were made in finalizing the guidance. The guidance announced in this notice finalizes the draft guidance dated March 2014.

II. Electronic Access

Persons with access to the Internet may obtain the guidance at either http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/default.htm or http://www.regulations.gov. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: June 10, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-14231 Filed: 6/15/2016 8:45 am; Publication Date: 6/16/2016]