4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

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

# Draft Guidance for Industry: Prior Notice of Imported Food Questions and Answers (Edition 3); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance entitled "Guidance for Industry: Prior Notice of Imported Food Questions and Answers (Edition 3)." The draft guidance addresses questions received since the publication of the second edition of the guidance in May 2004 and includes information related to the Food Safety Modernization Act (FSMA), which amended the Federal Food, Drug, and Cosmetic Act, to require the name of any country to which an article has been refused entry be reported in a prior notice. The draft guidance is intended to help the food industry and others comply with prior notice requirements.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Regulatory Affairs, Office of Food and Feed Operations, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993.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.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Anthony Taube, Office of Regulatory Affairs, Office of Food and Feed Operations, Division of Food Defense Targeting (HFC-180), Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 866-521-2297.

SUPPLEMENTARY INFORMATION:

## I. Background

We are announcing the availability of a draft guidance for industry entitled "Guidance for Industry: Prior Notice of Imported Food Questions and Answers (Edition 3)." In the Federal Register of May 3, 2004 (69 FR 24070), FDA issued a notice of availability of guidance entitled "Questions and Answers Regarding the Interim Final Rule on Prior Notice of Imported Food (Edition 2)." Since publication of edition 2 of the guidance, we have 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 (73 FR 66294; November 7, 2008) 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 (78 FR 32359; May 30, 2013). 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 and 2013 final rules, and include information about the new prior notice information requirement created by FSMA.

The Agency 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 and/or regulatory changes. As in the previous edition, 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.

This draft guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. Comments

Interested persons may submit either electronic comments regarding the draft guidance to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

## III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either http://www.fda.gov/FoodGuidances 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: March 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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