DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 2004D–0065]

Guidance for Industry: Questions and Answers Regarding the Interim Final Rule on Prior Notice of Imported Food (Edition 2); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability of guidance.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance entitled ''Questions and Answers Regarding the Interim Final Rule on Prior Notice of Imported Food (Edition 2).'' The guidance responds to various questions raised about section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the agency's implementing regulation, which require the submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the United States.

DATES: Submit written or electronic comments on the agency guidance at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Regulatory Affairs, Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Prior Notice Help Desk at 1–800–216–7331 or 301–575–0156, or FAX: 301–210–0247. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document. Submit written comments on the guidance to the Division of

Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Domenic Veneziano, Office of Regulatory Affairs, Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 866–521–2297.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 10, 2003 (68 FR 58974), FDA issued an interim final rule (IFR) to implement section 307 of the Bioterrorism Act. The prior notice regulation requires the submission to FDA beginning on December 12, 2003, of prior notice of food, including animal feed, that is imported or offered for import into the United States. On December 16, 2003, FDA issued the first edition of a guidance entitled ''Prior Notice of Imported Food Questions and Answers (Edition 1).'' This guidance entitled ''Questions and Answers Regarding the Interim Final Rule on Prior Notice of Imported Food (Edition 2)'' is a revision of the guidance published on December 16, 2003, and responds to additional questions about the prior notice IFR. It is intended to help the industry better understand and comply with the regulation in 21 CFR part 1, subpart I. FDA is issuing this guidance entitled ''Questions and Answers Regarding the Interim Final Rule on Prior Notice of Imported Food (Edition 2)'' as a level 1 guidance. Consistent with FDA's good guidance practices regulation (§ 10.115(g)(2) (21 CFR 10.115)(g)(2)), the agency will accept comments, but it is implementing the guidance document immediately, in accordance with § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. As

noted, the Bioterrorism Act requires prior notice submission to FDA starting on December 12, 2003. Clarifying the provisions of the IFR will facilitate timely and accurate prior notice submissions and thus, assist in the implementation of the IFR. FDA continues to receive a large number of questions regarding the prior notice IFR, and is responding to these inquires under § 10.115 as promptly as possible, using a question-and-answer format. The agency believes that it is reasonable to maintain all responses to questions concerning prior notice of imported food in a single document that is periodically updated as the agency receives and responds to additional questions. The following four indicators will be employed to help users of the guidance identify revisions: (1) The guidance will be identified as a revision of a previously issued document, (2) the revision date of the guidance will appear on its cover, (3) the edition number of the guidance will be included in its title, and (4) questions and answers that have been revised or added to the original guidance will be identified as such in the body of the guidance.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.cfsan.fda.gov/guidance.html*.

Dated: April 23, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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