Rules and Regulations

Federal Register
Vol. 69, No. 31
Tuesday, February 17, 2004

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 2003D–0545]

Guidance for Industry: Questions and Answers Regarding the Interim Final Rule on Registration of Food Facilities (Edition 3); 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 Registration of Food Facilities (Edition 3).'' The guidance responds to various questions raised about section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the agency's implementing regulation, which require facilities that manufacture/process, pack, or hold food for consumption in the United States to register with FDA by December 12, 2003.

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 registration help desk, 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: Melissa S. Scales, Office of Regulations and Policy (HFS–24), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1720.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 10, 2003 (68 FR 58894), FDA issued an interim final rule to implement section 305 of the Bioterrorism Act. The registration regulation requires facilities that manufacture/process, pack, or hold food (including animal feed) for consumption in the United States to register with FDA by December 12, 2003.

On December 4, 2003, FDA issued the first edition of a guidance entitled ''Questions and Answers Regarding the Interim Final Rule on Registration of Food Facilities.'' Subsequently, in the **Federal Register** of January 12, 2004 (69 FR 1675), FDA announced the availability of a revision of that guidance entitled ''Questions and Answers Regarding the Interim Final Rule on Registration of Food Facilities (Edition 2)''. This guidance entitled ''Questions and Answers Regarding the Interim Final Rule on Registration of Food Facilities (Edition 3)'' is a revision of the guidance announced on January 9, 2004, and responds to additional questions about the interim final rule on registration. It is intended to help the industry better understand and comply with the regulation in 21 CFR part 1, subpart H.

FDA is issuing this guidance entitled ''Questions and Answers Regarding the Interim Final Rule on Registration of Food Facilities (Edition 3)'' as a level 1 guidance. Consistent with FDA's good guidance practices regulation § 10.115(g)(2) (21 CFR 10.115), 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 that covered facilities be registered with FDA by December 12, 2003. Clarifying the provisions of the interim final rule will facilitate prompt registration by covered facilities and thus, complete implementation of the interim final rule.

FDA continues to receive a large number of questions regarding the registration interim final rule, 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 food facilities registration 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 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 on the guidance at any time. Two copies of any mailed comments are to be submitted, 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., Mondaythrough Friday.

III. Electronic Access

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

Dated: February 11, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–3421 Filed 2–12–04; 11:07 am]

BILLING CODE 4160–01–S