

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 4); 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 4)." 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:** You may submit comments, identified by Docket No. 2003D-0545, by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.

cf0458

2003D-0545

NAD 3

DDM  
Display Date 8-4-04  
Publication Date 8-6-04  
Certifier D. Hawkins

- E-mail: [fdadockets@oc.fda.gov](mailto:fdadockets@oc.fda.gov). Include Docket No. 2003D–0545 in the subject line of your e-mail message.
- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]:  
Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

*Instructions:* All submissions received must include the agency name and Docket No. or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to <http://www.fda.gov/ohrms/dockets/default/htm>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the “Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default/htm> 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.

**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.” The second edition of this guidance was issued on January 12, 2004, and the third edition on February 17, 2004. The guidance announced by this document entitled “Questions and Answers Regarding the Interim Final Rule on Registration of Food Facilities (Edition 4)” is a revision of the February 17, 2004, guidance and responds to additional questions about the interim final rule on registration. The guidance is intended to help the industry better understand and comply with the regulation in 21 CFR part 1, subpart H.

FDA wishes to highlight one issue clarified in the fourth edition of the food facility registration guidance, the appropriate designation of a U.S. agent by a foreign food facility. Since the interim final rule published, several individuals have notified FDA that, although listed in a facility’s registration as its U.S. agent, the individual had not agreed to serve as the facility’s U.S. agent. Question 14.20 in the fourth edition clarifies how FDA will handle the registration of a facility when the agency is notified that the individual listed as the facility’s U.S. agent disagrees with that designation.

FDA is issuing the guidance entitled “Questions and Answers Regarding the Interim Final Rule on Registration of Food Facilities (Edition 4)” as a level 1 guidance. Consistent with FDA’s good guidance practices (GGPs) regulation § 10.115 (21 CFR 10.115), the agency will accept comments on this guidance, but it is implementing the guidance 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 covered facilities to 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.

As noted in previous notices announcing the availability of guidance for food facility registration, FDA continues to respond to requests for clarification of the registration interim final rule by providing guidance in a question-and-answer format. The agency is maintaining all responses to questions concerning food facility registration in a single document that is periodically updated as the agency responds to additional questions. The following four indicators are 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) new questions and answers will be identified as such in the body of the guidance.

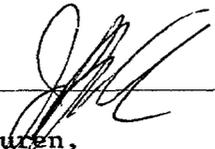
## **II. Comments**

Interested persons may, at any time, submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance. 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: 8/2/04  
August 2, 2004.



Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

**BILLING CODE 4160-01-S**

