

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 2005D–0356]

Guidance for Industry: Questions and Answers Regarding the Final Rule on Establishment and Maintenance of Records; 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 guidance for industry entitled “Questions and Answers Regarding Establishment and Maintenance of Records.” The guidance responds to various questions raised about the recordkeeping provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the agency’s implementing regulation, which requires the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. Such records are to allow for the identification of the immediate previous sources and the immediate subsequent recipients of food.

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

ADDRESSES: Submit written requests for single copies of the guidance entitled “Questions and Answers Regarding Establishment and Maintenance of Records” to Denise Beavers (see **FOR FURTHER INFORMATION CONTACT**). Send one self-addressed adhesive label to assist that office in processing your requests.

See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Denise Beavers, Center for Food Safety and Applied Nutrition (HFS–24), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1721.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 9, 2004 (69 FR 71562), FDA issued a final rule to implement section 306 of the Bioterrorism Act (21 U.S.C. 350c). The regulation requires the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. Such records are to allow for the identification of the immediate previous sources and the immediate subsequent recipients of food. Persons subject to the regulation are required to be in compliance by December 9, 2005, June 9, 2006, or December 11, 2006, depending on the size of the business.

The guidance for industry entitled “Questions and Answers Regarding Establishment and Maintenance of Records” responds to questions about the final rule on records. It is intended to help industry better understand and comply with the regulation in 21 CFR part 1, subpart J. FDA is issuing this guidance as a level 1 guidance. The guidance represents the agency’s current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. 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 final rule requires that covered persons begin to establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food by December 9, 2005, June 9, 2006, or December 11, 2006, depending on the size of the business. Clarifying the provisions of the final rule will facilitate prompt compliance with these requirements and ensure complete implementation of the final rule.

FDA continues to receive large numbers of questions regarding the records final rule, and is responding to these questions 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 establishment and maintenance of records 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 regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments and the guidance 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 guidance at *http://www.cfsan.fda.gov/guidance.html*.

Dated: September 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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