This document is scheduled to be published in the
Federal Register on 02/23/2012 and available online at
http://federalregister.gov/a/2012-04167, and on **FDsys.gov**

4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA-2011-D-0598]

Guidance for Industry: Questions and Answers Regarding Establishment and Maintenance of Records by Persons Who Manufacture, Process, Pack, Transport, Distribute, Receive, Hold, or Import Food (Edition 5)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of guidance availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Questions and Answers Regarding Establishment and Maintenance of Records by Persons Who Manufacture, Process, Pack, Transport, Distribute, Receive, Hold, or Import Food (Edition 5)." This guidance provides updated information pertaining to the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States under the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the FDA Food Safety and Modernization Act (FSMA) of January 4, 2011.

DATES: February 23, 2012. Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit electronic comments on the 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. Submit written requests for

single copies of the guidance to the Outreach and Information Center (HFS-009), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. 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.

FOR FURTHER INFORMATION CONTACT:

William A. Correll, Jr.,

Center for Food Safety and Applied Nutrition (HFS-607),

Food and Drug Administration,

5100 Paint Branch Pkwy.,

College Park, MD 20740,

240-402-1611.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled "Questions and Answers Establishment and Maintenance of Records by Persons Who Manufacture, Process, Pack, Transport, Distribute, Receive, Hold, or Import Food (Edition 5)," which replaces the fourth edition of a guidance of the same title issued in September 2006. The guidance is intended for persons who manufacture, process, pack, hold, or import human or animal foods intended for distribution to consumers, institutions, or food processors.

In the Federal Register of December 9, 2004 (69 FR 71562), FDA published a final rule implementing sections 414 and 704 of FD&C Act (21 U.S.C. 350c and 374) as amended by section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of

2002. The final rule 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. FSMA, signed into law on January 4, 2011 (Public Law 111-353), amended sections 414 and 704 of the FD&C Act by expanding FDA's access to records relating to foods that may cause serious adverse health consequences or death to humans or animals. In February 2012, FDA issued an interim final rule that revises § 1.361 (21 CFR 1.361) to reflect the FSMA amendments to the FD&C Act. This guidance document has been updated to reflect these changes.

On September 12, 2005, FDA issued the first edition of a guidance entitled "Questions and Answers Regarding the Establishment and Maintenance of Records." This document is the fifth edition of that guidance and is updated to reflect changes to the FD&C Act made by FSMA. This guidance is intended to provide individuals in the human and animal food industries with an updated overview of FDA's access to records. It provides practical information by answering common questions that cover a range of topics, including who is subject to records requirements, the scope of records retention and availability requirements, and the consequences of failing to establish and maintain required records or failing to make required records available to FDA. This guidance is being issued consistent with FDA's good guidance practices regulation § 10.115 (21 CFR 10.115) as a level 1 guidance. The Agency will accept comments, but it is implementing this document immediately, in accordance with § 10.115(g)(2) because the Agency has determined that prior public participation is not feasible or appropriate. The Agency made this determination because this guidance simply reflects the statutory changes made by section 101 of FSMA to sections 414 and 704 of the FD&C Act and seeks to remove any

confusion that might arise due to the existence of a guidance document that is inconsistent with the FD&C Act and its implementing regulations. In addition, much of this guidance remains the same as the guidance issued in September 2006.

This guidance represents the Agency's current thinking on its authority to access and copy records. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to information collection provisions found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). We conclude that the collection of information in § 1.361 is exempt from OMB review under 44 U.S.C. 18(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of a civil action to which the United States or any official or Agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an Agency against specific individuals or entities. The regulations in 5 CFR 1320.3(c) provide that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit or action, but only after a case file or equivalent is opened with respect to a particular party. Such a case file would be opened as part of the request to access records under § 1.361.

III. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. 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.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either http://www.fda.gov/FoodGuidances or http://www.regulations.gov. Always access an FDA guidance document by using the Web sites listed previously to find the most current version of the guidance.

Dated: February 17, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-4167 Filed 02/22/2012 at 8:45 am; Publication Date: 02/23/2012]