

relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency concludes that the IFR does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Comments

The requirements in this IFR will be in effect immediately upon publication in the **Federal Register**. FDA invites public comment on this IFR and will consider modifications to it based on comments made during the comment period when FDA issues the final rule. FDA intends to finalize this IFR 1 year from the close of the comment period.

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.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1 is amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for 21 CFR part 1 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 387, 387a, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. Section 1.361 is revised to read as follows:

§ 1.361 What are the record availability requirements?

When FDA has a reasonable belief that an article of food, and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, or when FDA believes that there is a reasonable probability that the use of or exposure to an article of food,

and any other article of food that FDA reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals, any records and other information accessible to FDA under section 414 or 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350c and 374(a)) must be made readily available for inspection and photocopying or other means of reproduction. Such records and other information must be made available as soon as possible, not to exceed 24 hours from the time of receipt of the official request, from an officer or employee duly designated by the Secretary of Health and Human Services who presents appropriate credentials and a written notice.

Dated: February 17, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-4165 Filed 2-22-12; 8:45 am]

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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 (Pub. L. 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.

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 59

RIN 2900–AN77

Due Date of Initial Application Requirements for State Home Construction Grants

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This final rule amends the Department of Veterans Affairs (VA) regulations concerning the calendar date by which VA must receive an initial application for a State Home Construction Grant in order for the application to be included on the priority list for the award of grants during the next fiscal year. We require that initial application materials must be received by VA no later than April

15, instead of August 15, of the year before the fiscal year in which the application would be considered for inclusion on the priority list for the award of grants. We require certification of State matching funds to be submitted no later than August 1, instead of August 15, in order for the project to be placed in priority group 1 of the priority list for the next fiscal year. The purpose of these changes is to ensure that VA has sufficient time to process all applications received and timely prepare the priority list, so that we can accurately notify States that VA intends to select and fund particular projects. We also make technical revisions to conform our regulations to these revisions.

DATES: This final rule is effective March 26, 2012.

FOR FURTHER INFORMATION CONTACT:

Vernon Wilkes, State Veterans Homes (10NA5), 1717 H Street NW., Washington, DC 20006, (202) 266–4617. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Under 38 U.S.C. 8131 through 8138, VA is authorized to award grants to assist States in constructing, remodeling, altering, or expanding State home facilities that will furnish specified types of care to veterans. VA has implemented this statutory authority at 38 CFR part 59.

Under 38 U.S.C. 8135, States that wish to receive assistance for a State home construction project (or acquisition of an existing facility to be used as a State home facility) must submit an application that includes certain information and documentation described in the statute. VA has implemented the application requirement in current § 59.20(a), which requires that applicants seeking inclusion on the priority list for grants awarded during the next fiscal year submit to VA an original and one copy of a completed VA Form 10–0388–1 and all information, documentation, and other forms specified by VA Form 10–0388–1. Under current § 59.20(c), VA encourages the submission of the application by April 15 but considers any application submitted before August 16 for inclusion on the priority list. VA maintains the "priority list" pursuant to current 38 CFR 59.50. Additionally, under current § 59.70(b), VA requires a State to commit funds for a project before August 16 in order for that project to be eligible for inclusion in priority group 1 of the priority list for the next fiscal year.

On March 1, 2011, VA published a proposed rule to improve the clarity and efficacy of the application process and