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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date 5-23-08
Publication Date 5-27-08
Certifier SPK

Food and Drug Administration

[Docket No. FDA-2008-N-0298]

**Reportable Food Registry as Required by the Food and Drug Administration
Amendments Act of 2007; Announcement of Delay in Implementation and
Request for Comments**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; delay in implementation and request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a delay in the implementation of the Reportable Food Registry (the Registry) of the Food and Drug Administration Amendments Act of 2007 (FDAAA). FDA intends to implement the FDAAA requirement to establish an electronic portal for reportable food by utilizing the business enterprise system currently under development by the agency. This system will be easy to use and the most efficient and cost effective for both users and the agency. FDA expects that the agency's business enterprise system will be operational in spring 2009. FDA acknowledges that the prohibited act provisions relating to the Registry will not apply until such time as FDA establishes the electronic portal to implement the Registry. In conjunction with this delay announcement, FDA is requesting comments on certain aspects of the Registry provisions.

DATES: Submit written or electronic comments by *[insert date 75 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061,

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Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Faye Feldstein, Center for Food Safety and Applied Nutrition (HFS-005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2428.

SUPPLEMENTARY INFORMATION:

I. Background

On September 27, 2007, the President signed FDAAA into law (Public Law 110-85). Section 1005 of FDAAA amends the Federal Food, Drug, and Cosmetic Act (the act) by creating a new section 417 (21 U.S.C. 350f). Section 417 of the act requires the Secretary of Health and Human Services (the Secretary) to establish within FDA a Reportable Food Registry (the Registry); the Registry is to be established not later than 1 year after the date of enactment (i.e., by September 27, 2008). The Congressionally-identified purpose of the Registry is to provide a “reliable mechanism to track patterns of adulteration in food [which] would support efforts by the Food and Drug Administration to target limited inspection resources to protect the public health” (121 Stat. 965). The Secretary has delegated to the Commissioner of Food and Drugs the responsibility for administering the act, including section 417 of the act.

To further the development of the Registry, section 417 of the act requires FDA to establish, also within 1 year after the date of enactment (i.e., by September 27, 2008), an electronic portal (the Reportable Food electronic portal) by which instances of reportable food may be submitted to FDA by responsible parties or public health officials.

Section 417(a)(1) of the act defines “responsible party” as a person that submits the registration under section 415(a) of the act (21 U.S.C. 350d) for

a food facility that is required to register under section 415(a), at which such article of food is manufactured, processed, packed, or held. Persons who are authorized to submit a facility registration under section 415 of the act are the owner, operator, or agent in charge of a domestic or foreign facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States. Section 417(a)(2) of the act defines a “reportable food” as an article of food (other than infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.

Under section 417(d) of the act, a responsible party is required to submit a report to FDA through the Reportable Food electronic portal as soon as practicable, but in no case later than 24 hours after the responsible party determines that an article of food is a reportable food. Federal, State, and local public health officials may voluntarily submit such reports to FDA through the electronic portal under section 417(d)(3) of the act. Section 417(e) of the act specifies 11 data elements that are required in the initial report or in a subsequent report to FDA; such reports are to be submitted via the Reportable Food electronic portal. Examples of required data elements include the following: (1) The registration numbers of the responsible party provided under section 415(a)(3) of the act; (2) the date on which the article of food was determined to be a reportable food; and (3) a description of the article of food including the quantity or amount.

Section 417(b)(2) of the act requires FDA to review promptly and assess information submitted via the electronic portal. Section 417(c)(1) requires FDA to issue, or cause to be issued, an alert or notification with respect to a reportable food using the information from the Registry as FDA deems

necessary to protect the public health. In addition, following submission of a report via the Reportable Food electronic portal and after consultation with the responsible party that submitted a report, FDA may require the responsible party to provide a notification consistent with section 417(d)(6)(B) of the act. Section 1005(e) of FDAAA provides that the requirements of section 417(d) of the act are effective 1 year after the enactment date (i.e., on September 27, 2008). The failure to submit a report or provide a notification required by section 417(d) of the act is a prohibited act under section 301(mm) of the act (21 U.S.C. 331(mm)); persons who commit a prohibited act may be enjoined (21 U.S.C. 332) or prosecuted criminally (21 U.S.C. 333).

Under section 1005(f) of FDAAA, FDA is required to issue a guidance to industry about submitting reports to the electronic portal established under section 417(b)(1) of the act and providing notifications to other persons in the supply chain of an article of food. This guidance is required to be issued not later than 9 months after the date of enactment of FDAAA (i.e., by June 27, 2008).

II. Delay in Implementation of the Registry

FDA has determined that the most efficient and cost effective means of implementing the requirements of section 417 of the act relating to the Registry is to utilize the business enterprise system currently under development within the agency. This system will permit FDA to establish an electronic portal through which instances of reportable food may be submitted to the agency, and will be easy to use, for both those submitting reports to the agency and for FDA. However, the agency anticipates that FDA's business enterprise system will not be implemented in time to meet the statutory deadline of section 417(b)(1) of the act which, as stated, requires FDA to establish the

Reportable Food electronic portal by September 27, 2008. Therefore, FDA is announcing a delay in the implementation of the requirements of section 417 of the act.

FDA expects that the agency's business enterprise system will be operational in spring 2009. In a future issue of the **Federal Register**, the agency will notify the public, including the industry, of the date the Reportable Food electronic portal becomes available to accept reports under section 417(d) of the act. After that date, FDA expects that responsible parties will comply with the requirements of section 417 of the act, including the requirement to submit instances of reportable food to the agency via the Reportable Food electronic portal. In the interim, FDA strongly encourages persons to continue to report instances of adulterated food through existing mechanisms, such as notifying the relevant FDA District office, until such time as the Registry and its associated electronic portal are fully implemented.

III. Request for Comments

FDA is seeking comments on the requirements contained in the Registry provisions of section 417 of the act. In addition to general information, data, and comments, we request comments on the following questions:

(1) What obstacles, if any, do responsible parties anticipate in complying with the requirements of section 417 of the act?

(2) How can FDA enhance the quality, utility, and clarity of the information to be submitted to the Registry?

(3) What would be an efficient and effective method for providing and receiving notifications to and from sources and recipients in the supply chain of instances of reportable food?

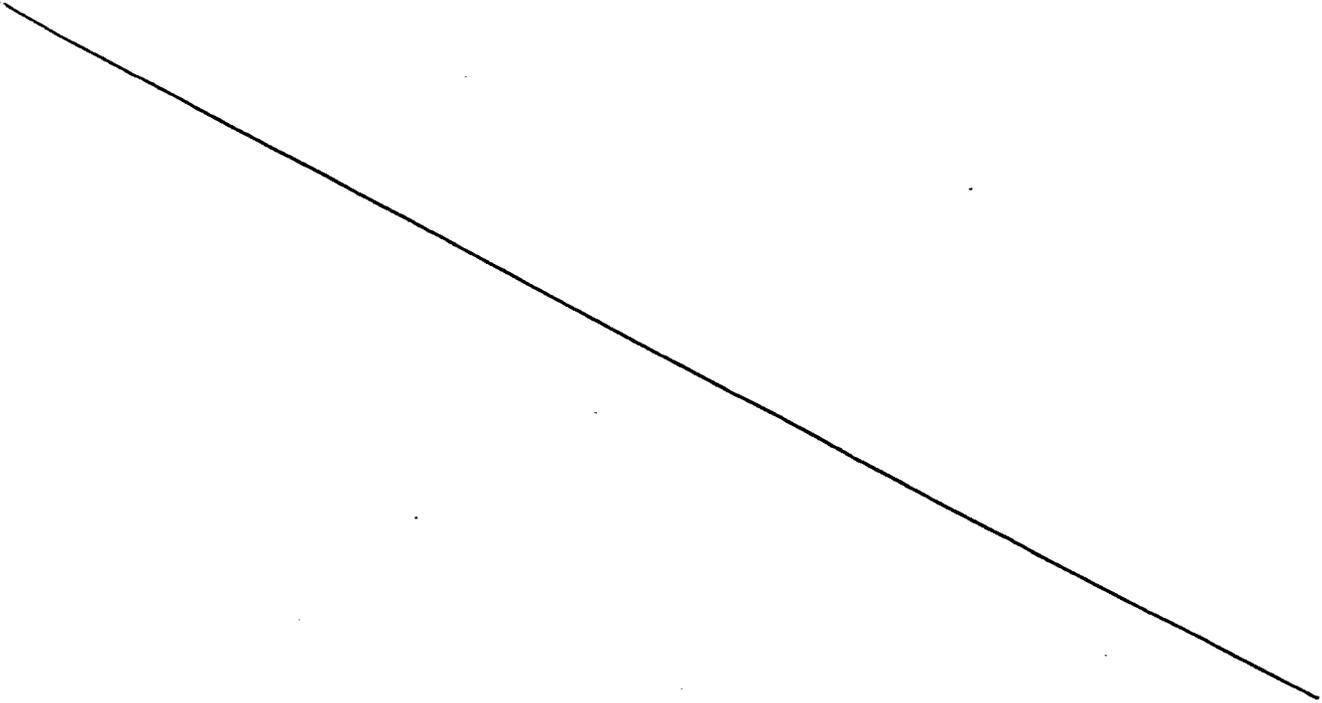
(4) In addition to the data elements set out in section 417 of the act, what other information, if any, would be important to provide in responsible party

notifications to the immediate previous source and immediate subsequent recipient of the article of food?

IV. Comments

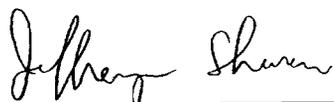
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *<http://www.regulations.gov>*.



Dated: May 16, 2008

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Jeffrey Shuren
Associate Commissioner for Policy and Planning

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

BILLING CODE 4160-01-S

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