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# Guidance for Industry

## Questions and Answers Regarding Mandatory Food Recalls

### *Draft Guidance*

**This guidance is being distributed for comment purposes only.**

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments 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. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the ORA Office of Enforcement and Import Operations (OEIO) at 301-796-8209.

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Office of Regulatory Affairs  
Center for Food Safety and Applied Nutrition  
Center for Veterinary Medicine**

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# **Guidance for Industry<sup>1</sup>**

## **Questions and Answers Regarding Mandatory Food Recalls**

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

### **I. INTRODUCTION**

The purpose of this document is to provide guidance to industry on the implementation of the mandatory food recall provisions of Section 423 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), which was added by Section 206 of the FDA Food Safety Modernization Act of 2011 (FSMA). The guidance in this document is in the form of Questions and Answers and provides answers to common questions that might arise about these mandatory recall provisions and FDA's current thinking regarding their implementation.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

### **II. BACKGROUND**

FDA's mandatory food recall authority went into effect when FSMA was enacted on January 4, 2011. Section 423 of the FD&C Act, as added by Section 206 of FSMA, gives FDA the authority to order a responsible party to recall an article of food where FDA determines that there is a reasonable probability that the article of food (other than infant formula) is adulterated under section 402 of the FD&C Act [21 U.S.C. § 342] or misbranded under section 403(w) of the FD&C Act [21 U.S.C. § 343(w)] and that the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals (SAHCODHA).

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<sup>1</sup> This guidance has been prepared by the Office of Enforcement and Import Operations in the Office of Regulatory Affairs in cooperation with the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine at the U.S. Food and Drug Administration.

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### **III. QUESTIONS AND ANSWERS**

This list of Questions and Answers is intended to provide answers to common questions about the mandatory recall provisions in section 423 of the FD&C Act and FDA’s current thinking regarding their implementation.

#### **1. Why is mandatory food recall authority important?**

Before FSMA was enacted, FDA relied on responsible parties to voluntarily recall violative food products (except infant formula recalls which are described under section 412 of the FD&C Act). FDA continues to rely on responsible parties to voluntarily recall violative food products; however, FSMA’s mandatory recall authority allows FDA to mandate a recall when a responsible party chooses not to conduct a voluntary recall when the criteria under section 423 of the FD&C Act are met. FDA can use its mandatory recall authority when FDA determines that there is a reasonable probability that an article of food is adulterated under section 402 of the FD&C Act and/or misbranded under section 403(w) of the FD&C Act and where there is a reasonable probability that the use of or exposure to such food would cause SAHCODHA.

#### **2. What foods are subject to FDA’s mandatory food recall authority?**

The articles of food that are subject to FDA’s mandatory recall authority are all articles of food (other than infant formula) that are manufactured, processed, packed, or held at a food facility that is required to register under section 415(a) of the FD&C Act. Infant formula is not covered under section 423 because it has its own recall requirements under section 412 of the FD&C Act.

The term “food” refers to (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article (section 201(f) of the FD&C Act [21 U.S.C. § 321(f)]).

The term “food” includes dietary supplements, which are deemed to be food under the FD&C Act (section 201(ff) of the FD&C Act [21 U.S.C. § 321(ff)]). The term “dietary supplement” refers, with certain exceptions, to a product that is labeled as a dietary supplement, is intended for ingestion, is intended to supplement the diet, and contains at least one dietary ingredient. Dietary ingredient(s) in these products include: vitamins, minerals, herbs or other botanicals, amino acids, and substances for use by man to supplement the diet by increasing total dietary intake. Dietary ingredients can also be extracts, metabolites, constituents, concentrates, or a combination of any of the above-mentioned dietary ingredients.

#### **3. What is a responsible party under section 423 of the FD&C Act?**

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The responsible party with respect to an article of food under section 423 of the FD&C Act, is defined under section 417 of the FD&C Act. Section 417(a)(1) defines the term “responsible party” as a person who submits the registration under section 415(a) of the FD&C Act [21 U.S.C. 350d(a)] 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. “Person” is defined in section 201(e) of the FD&C Act [21 U.S.C. 321(e)] as including individuals, partnerships, corporations and associations. As such, the owner, operator, or agent in charge of a facility who is responsible for submitting the registration is also responsible for implementing and assuring the recall is performed, if so ordered under section 423 of the FD&C Act.

#### **4. When do the mandatory recall provisions go into effect?**

FDA’s mandatory recall authority under section 423 of the FD&C Act, added by section 206 of FSMA, became effective when President Obama signed FSMA into law on January 4, 2011.

#### **5. What are the criteria for a mandatory recall?**

A couple of conditions must exist before FDA can use its mandatory recall authority under section 423 of the FD&C Act.

First, FDA has to make the determination that there is a reasonable probability that the article of food (other than infant formula) is adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act.

Second, FDA has to make a determination that there is a reasonable probability that the use of or exposure to such food will cause SAHCODHA.

#### **6. What is the process FDA must follow for a mandatory recall?**

Once FDA has determined that the criteria for a mandatory recall have been met, FDA must first provide the responsible party (as defined in section 417(a)(1) of the FD&C Act) with an opportunity to voluntarily cease distribution and recall the article of food. FDA will provide the opportunity to voluntarily cease distribution and recall to the responsible party in written form using an expeditious method. If the responsible party refuses or does not voluntarily cease distribution and recall the article of food within the time and manner prescribed by FDA, if so prescribed, FDA may order the responsible party to cease distributing the article of food, order the responsible party to give notice to certain other persons to cease distributing the article of food, and give the responsible party an opportunity for an informal hearing. After these steps are completed, FDA may order a recall under section 423(d) of the FD&C Act if it is determined that the removal of the article from commerce is necessary. Only the FDA Commissioner has the authority to order a recall under section 423(d). Recall orders under Section 423(d) may, if necessary, be vacated by the Commissioner.

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**7. When is a food considered adulterated under Section 402 of the FD&C Act?**

Section 402 of the FD&C Act includes many reasons a food may be adulterated including:

- If the food bears or contains any poisonous or deleterious substance which may render it injurious to health; consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food; or has been prepared, packed, or held under insanitary conditions whereby it may be rendered injurious to health;
- If the food is a dietary supplement or contains a dietary ingredient that presents a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling; is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury; or is a dietary supplement declared by the Secretary to pose an imminent hazard to public health or safety.

**8. When is a food considered misbranded under 403(w) of the FD&C Act?**

Section 403(w) refers to product labeling required to be present if a food, other than a raw agricultural commodity, bears or contains a major food allergen. Major food allergens are defined at section 201(qq) of the FD&C Act [21 U.S.C. 321(qq)] as milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, soybeans, and any food ingredients that contain a protein derived from these foods (with limited exceptions noted under section 201(qq)(2)). Under section 403(w), a food, other than a raw agricultural commodity, is misbranded if it bears or contains a major food allergen and the label for the food does not identify the name of the food source from which the major food allergen is derived, either through a “Contains” statement or in the ingredient list, as specified under section 403(w).

**9. What evidence might FDA consider when deciding to move forward with a mandatory food recall under Section 423?**

FDA will evaluate all applicable evidence, when determining whether there is a reasonable probability the article of food (other than infant formula) is adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act and that the use of or exposure to such article will cause SAH/CODHA. Evidence may include:

- Observations made during inspections of the responsible party or other parties;
- Results from sample analyses;
- Epidemiological data;
- Reportable Food Registry data; and
- Consumer and trade complaints.

**10. How will FDA publicize information about the mandatory recall?**

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In accordance with Section 423(g) of the FD&C Act, FDA will ensure that a press release is published regarding the recall, as well as alerts and public notices, as appropriate, to provide notification to affected consumers and retailers. The publication will include, at a minimum, the name of the article of food subject to recall, a description of the risks associated with the food, and to the extent practical, information about similar articles of food that are not affected by the recall.

**11. When would user fees to cover food recall activities be assessed, to whom, and for what activities? What are the costs of the fees? Can civil money penalties be assessed for not complying with a recall order?**

Section 743(a)(1)(B) of the FD&C Act authorizes the collection of fees from a responsible party for a domestic facility as defined under 415(b) and an importer who does not comply with a food recall order under section 423 or under section 412(f) of the FD&C Act (infant formula recalls). The fees would cover time spent by FDA conducting food recall activities, including technical assistance, follow-up effectiveness checks, and public notifications. Noncompliance may include the following: (1) Not initiating a recall as ordered by FDA; (2) not conducting the recall in the manner specified by FDA in the recall order; or (3) not providing FDA with requested information regarding the recall, as ordered by FDA.

FDA publishes a Federal Register notice of fees for non-compliance with a Recall Order no later than 60 days before the start of each fiscal year.

FSMA amended Section 303(f)(2)(A) of the FD&C Act [21 U.S.C. 333(f)(2)(A)] to permit FDA to assess civil money penalties to any person who does not comply with a recall order under Section 423.

For more information on the Food Safety Modernization Act, go to:  
<http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>

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