Report to Congress

Annual Report on the Use of Mandatory Recall Authority

FY 2023

Report in Response to Section 206(f) of the FDA Food Safety Modernization Act (Public Law 111-353)

Executive Summary

On January 4, 2011, the FDA Food Safety Modernization Act (FSMA) (Public Law 111-353) was signed into law. Section 206(a) of FSMA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to add section 423 (21 U.S.C. 350l), giving the Food and Drug Administration (FDA) mandatory recall authority over responsible parties under certain circumstances, with respect to FDA-regulated foods other than infant formula.

FSMA requires the Department of Health and Human Services (HHS) to submit an annual report to Congress on (1) the use of this recall authority under section 423 of the FD&C Act and (2) any public health advisories issued by FDA that advise against the consumption of an article of food on the ground that it is adulterated and poses an imminent danger to health. In Fiscal Year 2023, FDA performed no reportable mandatory recall activities of a food product.

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I. Introduction

On January 4, 2011, the FDA Food Safety Modernization Act (FSMA) (Public Law 111-353) was signed into law. Section 206(a) of FSMA amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) to add section 423 (21 U.S.C. 350l), granting the Food and Drug Administration (FDA or the Agency) mandatory recall authority over responsible parties[1] under certain circumstances, with respect to FDA-regulated foods other than infant formula.[2]

FSMA requires the Department of Health and Human Services (HHS) to submit an annual report to Congress on (1) the use of this recall authority under section 423 of the FD&C Act and (2) any public health advisories issued by FDA that advise against the consumption of an article of food on the ground that it is adulterated and poses an imminent danger to health. Specifically, section 206(f) of FSMA states:

> *(1) In general.--Not later than 2 years after the date of enactment of this Act and annually thereafter, the Secretary of Health and Human Services (referred to in this subsection as the "Secretary") shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the use of recall authority under section 423 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) and any public health advisories issued by the Secretary that advise against the consumption of an article of food on the ground that the article of food is adulterated and poses an imminent danger to health.*
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> *(2) Content.--The report under paragraph (1) shall include, with respect to the report year—*
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> > *(A) the identity of each article of food that was the subject of a public health advisory described in paragraph (1), an opportunity to cease distribution and recall under subsection (a) of section 423 of the Federal Food, Drug, and*

[1] 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. Specifically, 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. See https://www.fda.gov/media/117429/download.

[2] Infant formula recalls are conducted under section 412 of the FD&C Act [21 U.S.C. § 350a] . See https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterIVFood/default.htm.

Cosmetic Act, or a mandatory recall order under subsection (b) of such section;

(B) the number of responsible parties, as defined in section 417 of the Federal Food, Drug, and Cosmetic Act, formally given the opportunity to cease distribution of an article of food and recall such article, as described in section 423(a) of such Act;

(C) the number of responsible parties described in subparagraph (B) who did not cease distribution of or recall an article of food after given the opportunity to cease distribution or recall under section 423(a) of the Federal Food, Drug, and Cosmetic Act;

(D) the number of recall orders issued under section 423(b) of the Federal Food, Drug, and Cosmetic Act; and

(E) a description of any instances in which there was no testing that confirmed adulteration of an article of food that was the subject of a recall under section 423(b) of the Federal Food, Drug, and Cosmetic Act or a public health advisory described in paragraph (1).

This is the eleventh such annual report submitted to Congress by HHS since FSMA was enacted. This report covers the reporting requirements related to the use of FDA's recall authority under section 423 of the FD&C Act during Fiscal Year (FY) 2023. For this report, given that the requirement to report "public health advisories" was imposed by the same section of FSMA that granted FDA mandatory recall authority under section 423 of the FD&C Act, the Agency is interpreting the phrase "public health advisories" to apply only to communications made to the public after the mandatory recall process was initiated (i.e., after a letter under section 423 of the FD&C Act has been sent). FDA issues many other types of communications (e.g., consumer advisories, warning letters, and reports of outbreak investigations) that may advise against the consumption of specific articles of food, notify the public of a danger to health, or indicate that a food is adulterated. These various and important communications are available on FDA's website.[3] However, these are not "public health advisories" as described in section 206(f) of FSMA; therefore, FDA is not including them in this report.

II. Background

FSMA enables FDA to better protect the public health by strengthening food safety measures. Under FSMA, FDA has several effective enforcement tools to protect the

[3] See links at http://www.fda.gov/food/default.htm.

food supply. These enforcement tools include the authority to issue a mandatory recall order under section 423 of the FD&C Act for an article of food other than infant formula. FDA can use its mandatory recall authority under section 423 when it determines there is a "reasonable probability" that the food is adulterated under section 402 or misbranded under section 403(w) of the FD&C Act and that the use of or exposure to such food will cause serious adverse health consequences or death to humans or animals.

To issue such a mandatory recall order, FDA must first provide the responsible party with an opportunity to voluntarily cease distribution and recall the article of food (section 423(a) of the FD&C Act). If the responsible party refuses to or does not voluntarily cease distribution and recall such article of food within the time and in the manner prescribed by FDA, the Agency may order the responsible party to immediately cease distributing the article of food and give notice to certain other persons to cease distributing the article of food, as set forth in section 423(b) of the FD&C Act. Should FDA order the responsible party to cease distribution and to give notice to certain other persons, section 423(c) of the FD&C Act specifies that FDA must provide the responsible party with the opportunity to request an informal hearing, to be held not later than 2 days after issuance of the order, on the actions required by the order and on why the article that is the subject of the order should not be recalled. If, after providing an opportunity for an informal hearing, FDA determines that removal of the article from commerce is necessary, then FDA will, as appropriate, amend the order to require recall of such article or other appropriate action, specify a timetable for the recall, require periodic reports describing the progress of the recall, and provide notice to consumers to whom such article was, or may have been, distributed. Alternatively, if, after such hearing, FDA determines that adequate grounds do not exist to continue the actions required by the order, or that such actions should be modified, then FDA will vacate or modify the order as appropriate.

III. Use of Mandatory Recall Authority

In FY 2023, FDA performed no reportable mandatory recall activities for a food product and did not issue any "public health advisories" as described in section 206(f) of FSMA.

This report was prepared by FDA's Office of Food Policy and Response.
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