

**2016**

**Report to Congress**

**Fiscal Year 2016 Annual Report to Congress on the Use of Mandatory Recall Authority  
Submitted Pursuant to Section 206 of the FDA Food Safety Modernization Act,  
Public Law 111-353**

**U.S. Department of Health and Human Services**

**Food and Drug Administration**

**Date** \_\_\_\_\_

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## Introduction

On January 4, 2011, the President signed into law the FDA Food Safety Modernization Act (FSMA) (Public Law 111-353). 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) giving the Food and Drug Administration (FDA or the Agency), for the first time, mandatory recall authority over responsible parties with respect to all FDA-regulated foods other than infant formula.<sup>1</sup> FSMA requires the Department of Health and Human Services (HHS) to submit a report to Congress on the use of recall authority under section 423 of the FD&C Act and any public health advisories issued by FDA that advise against the consumption of an article of food on the grounds that it is adulterated and poses an imminent danger to health. Specifically, FSMA section 206(f) 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 [[Page 124 STAT. 3944]] 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.*

*(2) Content.--The report under paragraph (1) shall include, with respect to the report year--*

- (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 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 fourth annual report to this mandate since FSMA was enacted. It covers the reporting requirements relating to the use of recall authority under section 423 of the FD&C Act during Fiscal Year (FY) 2016. 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 term “public health advisories” in

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<sup>1</sup> Infant formula recalls are conducted under sections 412(e), (f), and (g) of the FD&C Act.  
<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAAct/FDCAActChapterIVFood/>

this context to apply only to communications made to the public when the mandatory recall process has been initiated (i.e., 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.<sup>2</sup> However, since these are not "public health advisories" as described in section 206(f) of FSMA, FDA is not including them in this report.

## **Background**

FSMA enables FDA to better protect public health by strengthening food safety measures. Under FSMA, FDA has several effective enforcement tools to protect the 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, for which FDA 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 that food will cause serious adverse health consequences or death to humans or animals.<sup>3</sup>

In order to issue such a mandatory recall order, FDA must first provide the responsible party with the opportunity to cease distribution and to conduct a voluntary recall of the article of food in question. If the responsible party refuses to, or does not voluntarily cease distribution or recall such food within the time and in the manner prescribed by FDA, the Agency may proceed under the mandatory recall authority as set forth in section 423 of the FD&C Act. Should the Secretary order the responsible party to cease distribution and to give notice to other persons in the distribution chain, the responsible party has the opportunity to request a hearing to be held within 2 days to contest the order and convince FDA that the article of food should not be recalled.

Prior to the enactment of FSMA, FDA generally had to rely upon manufacturers' voluntary recall efforts or obtain a court order to remove contaminated or misbranded foods, other than infant formula, from the food supply.

## **Use of Recall Authority**

In FY 2016, FDA had no mandatory recall activity to report under section 423 of the FD&C Act. As a result, FDA did not issue any public health advisories as described in section 206(f) of FSMA.

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<sup>2</sup> See links at <http://www.fda.gov/food/default.htm>.

<sup>3</sup> Specifically, section 423(a) of the FD&C Act provides for FDA to take action where "the Secretary determines, based on information gathered through the reportable food registry under section 417 or through any other means, that there is a reasonable probability that an article of food (other than infant formula) is adulterated under section 402 or misbranded under section 403(w) and the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals." (21 U.S.C. 350*l*)