Report to Congress

Fiscal Year 2018 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

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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), giving the Food and Drug Adminstration (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.[1] 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 sixth annual report in response 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) 2018. Given that the requirement to report "public health

[1] Infant formula recalls are conducted under sections 412(e), (f), and (g) of the FD&C Act: https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterIVFood/default.htm.

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 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.[2] 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.[3]

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 2018, FDA issued one mandatory recall order of a food product under section 423 of the FD&C Act. After a number of Triangle Pharmanaturals LLC's in-process products and finished products tested positive for *Salmonella*, FDA determined that there was a reasonable probability that all food products containing powdered kratom manufactured, processed, packed, or held by Triangle Pharmanaturals LLC were adulterated under section 402(a)(1) (21 U.S.C. 342(a)(1)) of

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

[3] 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*).

the FD&C Act[4] and that there was a reasonable probability that the use or exposure to such products would cause serious adverse health consequences or death to humans or animals due to contamination with *Salmonella*. After first sending a letter under section 423(a) of the FD&C Act asking the firm to voluntarily cease distribution and recall such products, FDA ultimately issued a mandatory recall order in April of 2018 for all food products containing powdered kratom manufactured, processed, packed, or held by Triangle Pharmanaturals LLC, including:

- "Raw Form Organics Maeng Da Kratom Emerald Green" in 300-capsule plastic bottles;
- "Raw Form Organics Maeng Da Kratom Ivory White" in 300-capsule plastic bottles; and
- "Raw Form Organics Maeng Da Kratom Ruby Red" in 300-capsule plastic bottles;

As a result, FDA issued a public health advisory as described in section 206(f) of FSMA on April 3, 2018.[5] This was the first time the Agency has issued a mandatory recall order under section 423(d) of the FD&C Act to protect Americans from contaminated food products.

[4] Under section 402(a)(1) of the FD&C Act, a food is deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health.

[5] See FDA announcements at: https://www.fda.gov/news-events/press-announcements/fda-orders-mandatory-recall-kratom-products-due-risk-salmonella.