DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

June 8, 2016

**TO:** Robert M. Califf, M.D.
Commissioner of Food and Drugs
Food and Drug Administration

**FROM:** /Daniel R. Levinson/
Inspector General

**SUBJECT:** Early Alert: The Food and Drug Administration Does Not Have an Efficient and Effective Food Recall Initiation Process (A-01-15-01500)

The purpose of this memorandum is to alert you to a preliminary finding from our ongoing audit of the Food and Drug Administration (FDA) food recall program. One of the objectives of our audit is to determine whether FDA has an efficient and effective food recall initiation process that helps ensure the safety of the Nation's food supply.

We found that FDA did not have an efficient and effective food recall initiation process that helps ensure the safety of the Nation's food supply. Specifically, FDA did not have policies and procedures to ensure that firms[1] or responsible parties[2] (collectively referred to in this document as "firms") initiated voluntary food recalls promptly. This issue is a significant matter and requires FDA's immediate attention.

We suggest that FDA update its policies and procedures to instruct its recall staff to establish set timeframes for (1) FDA to request that firms voluntarily recall their products and (2) firms to initiate voluntary food recalls.

Our audit is a followup of our June 2011 report, *Review of the Food and Drug Administration's Monitoring of Imported Food Recalls* (A-01-09-01500). In that audit, we found FDA's food recall program was inadequate because FDA did not have the authority to require firms to recall certain foods and FDA did not always follow its own procedures. To help ensure the safety of the Nation's food supply, we recommended that FDA consider our findings when implementing the FDA Food Safety Modernization Act (FSMA) and follow its own procedures for monitoring recalls. FDA agreed with our recommendations.

[1] See 21 CFR part 7, subpart C.

[2] Under section 423 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), a "responsible party" means a person who submits the registration under section 415(a) of the FD&C Act for a food facility that is required to register under section 415(a) of the FD&C Act.

## BACKGROUND

FDA generally relies on firms to voluntarily recall harmful articles of food.[3] Before 2011, FDA did not have the authority to require a firm to recall certain articles of food. However, the FSMA added section 423 to the FD&C Act,[4] which gives FDA the authority to order a firm to recall certain articles of food after FDA determines that there is a reasonable probability that the food is adulterated or misbranded and that it will cause serious adverse health consequences or death to humans or animals (this is commonly referred to as SAHCODHA). FDA has used its authority under FSMA twice.[5]

Before issuing a mandatory recall order, FDA must provide the firm with an opportunity to voluntarily recall the product. FDA may require that the firm complete the recall in a prescribed timeframe. If the firm refuses or fails to complete the recall, FDA may order the firm to cease its distribution. After the firm is given an opportunity for an informal hearing, FDA may order the product's recall and specify a recall timetable.

We selected a judgmental sample of 30 imported and domestic voluntary human food recalls reported to FDA between October 1, 2012, and May 4, 2015.[6] We performed site visits at 7 of the 11 FDA district offices responsible for monitoring the 30 recalls to conduct interviews and review recall files. We obtained recall files electronically from the remaining four district offices.

## PRELIMINARY AUDIT RESULTS

We found that FDA did not have an efficient and effective food recall initiation process that helps ensure the safety of the Nation's food supply. Specifically, we found that FDA's policies and procedures did not instruct its recall staff to prescribe to the firms a time and a manner in which to initiate the voluntary recall. We also found that FDA did not have policies and procedures to ensure that firms initiated voluntary food recalls promptly.

For all 30 voluntary recalls in our sample, after FDA first became aware that an adulterated or misbranded product could be in the food supply chain, it did not prescribe a timeline for each firm to initiate a recall. For two recalls, the firms did not initiate the recall of all potentially harmful products until 165 days and 81 days after FDA became aware of the potential

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[3] See 21 CFR part 7, subpart C.

[4] Section 206 of the FSMA, P.L. No. 111-353 (enacted January 4, 2011).

[5] In September 2012, FDA became aware of pet food distributed by Kasel Associates Industries, Inc., that was adulterated with *Salmonella*, a pathogenic organism, and initiated its mandatory recall authority for the first time in February 2013. In September 2013, FDA become aware of dietary supplements distributed by USP Labs that were adulterated with aegeline (a new ingredient for which there was inadequate information to provide reasonable assurance that it would not present a significant or unreasonable risk of injury or illness) and initiated its mandatory recall authority for the second time in November 2013.

[6] We selected recalls by considering certain risk factors, including but not limited to the recall classification, length of time for the firm to initiate a recall, and length of time for the FDA to classify a recall.

contaminations. The delays in the firms' recalls may have occurred because FDA did not have policies and procedures that instruct its recall staff to establish set timeframes for (1) FDA to request that firms voluntarily recall their products and (2) firms to initiate voluntary food recalls. As a result, consumers remained at risk of illness or death for several weeks after FDA knew of potentially hazardous food.

For example:

- In a recall involving nut butter,[7] at least 14 people became ill with a strain of *Salmonella*[8] indistinguishable from or linked to the strain found at the firm's manufacturing facility. 165 days passed from the date FDA identified the potentially adulterated product and the date the firm initiated a voluntary food recall. See Attachment A for a timeline of events for this recall.

- In a series of recalls involving various cheese products,[9] at least nine people became ill from *Listeria monocytogenes*,[10] including one infant who died. According to FDA records, the Centers for Disease Control and Prevention (CDC) also linked two fetal losses to these illnesses. 81 days passed from the date FDA became aware of the adulterated product and the date the firm had voluntarily recalled all affected products. See Attachment B for a timeline of events for this recall.

**CONCLUSION**

FDA does not have adequate policies and procedures to ensure that firms take prompt and effective action in initiating voluntary food recalls. As a result, consumers remained at risk of illness or death for several weeks after FDA was aware of a potentially hazardous food in the supply chain.

We suggest that FDA revise its policies and procedures to instruct recall staff to establish set timeframes for (1) FDA to request that firms voluntarily recall their products and (2) firms to initiate voluntary food recalls.

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[7] The firm that voluntarily conducted the recall was nSpired Natural Foods, Inc.

[8] *Salmonella* is a pathogenic organism that can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Healthy individuals may suffer short-term symptoms such as severe diarrhea, bloody diarrhea, fever, chills, abdominal discomfort, and occasionally vomiting.

[9] The firm that voluntarily conducted the recall was Oasis Brands, Inc.

[10] *Listeria monocytogenes* is an organism that can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Healthy individuals may suffer only short-term symptoms such as a high fever, severe headache, stiffness, nausea, abdominal pain, and diarrhea. *Listeria* infection can cause miscarriages and stillbirths among pregnant women.

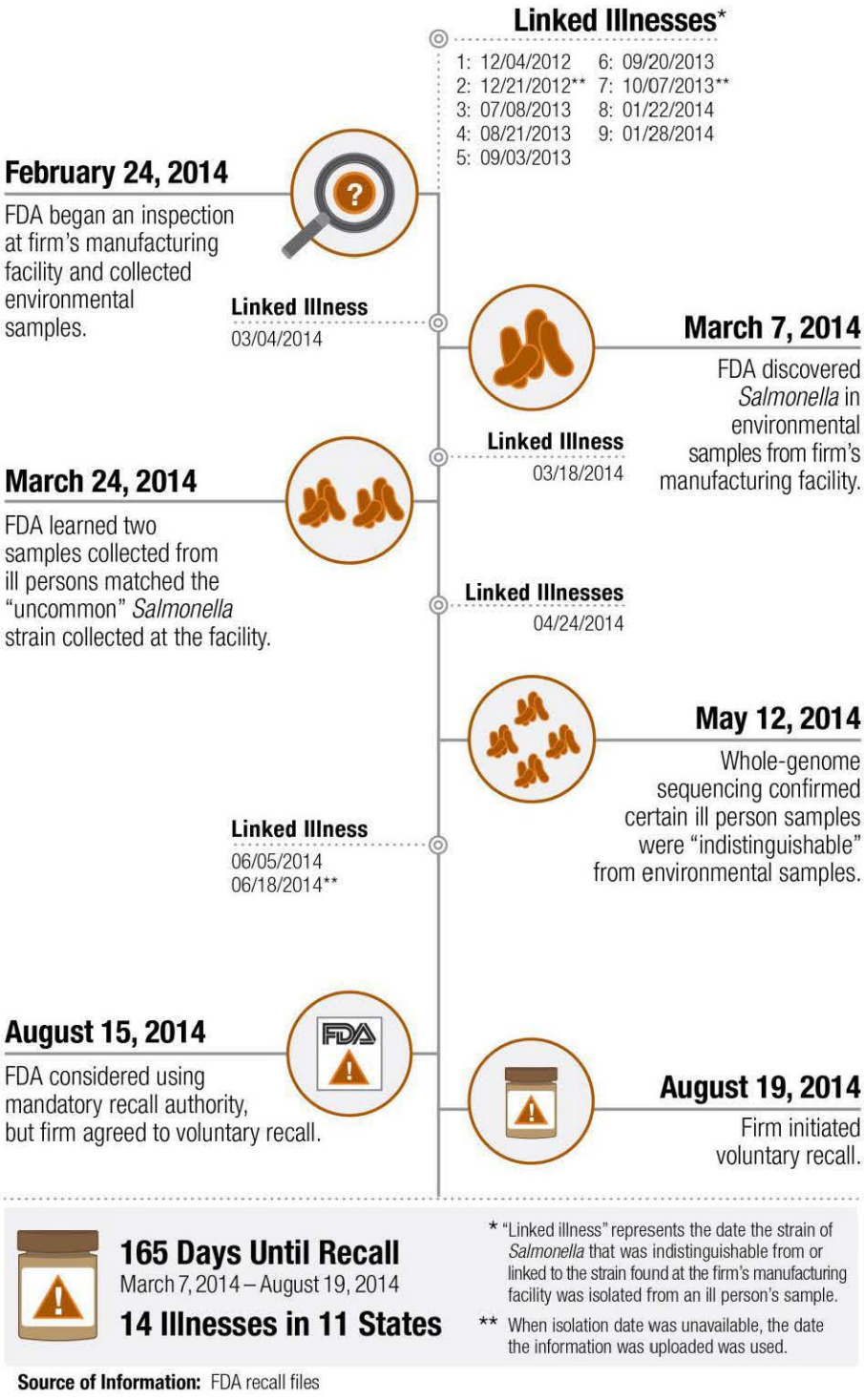
The information in this early alert is preliminary, and the audit is continuing. We will issue a draft report at the conclusion of the audit and include comments and actions taken in response to this early alert.

If you have any comments or questions about this memorandum, please do not hesitate to call me, or your staff may contact Amy J. Frontz, Assistant Inspector General for Audit Services, at (202) 619-1157 or through email at Amy.Frontz@oig.hhs.gov.

Attachments

# ATTACHMENT A

In a recall involving nut butter, at least 14 people became ill with a strain of *Salmonella* indistinguishable from or linked to the strain found at the firm's manufacturing facility. 165 days passed from the date FDA identified the potentially adulterated product and the date the firm initiated a voluntary food recall.



# ATTACHMENT B

In a series of recalls involving various cheese products, at least nine people became ill from *Listeria monocytogenes*, including one infant who died. According to FDA records, the CDC also linked two fetal losses to these illnesses. 81 days passed from the date FDA became aware of the adulterated product and the date the firm had voluntarily recalled all affected products.