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Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

**Safety of the U.S. Food Supply: Continuing Concerns Over the Food and
Drug Administration's Food-Recall Process**

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Good morning, Chairman Harper, Ranking Member DeGette, and Members of the Subcommittee. I am Gloria Jarmon, Deputy Inspector General for Audit Services for the Office of Inspector General (OIG), U.S. Department of Health and Human Services. I appreciate the opportunity to appear before you to discuss our recently published audit report on the food-recall process at the Food and Drug Administration (FDA) and our recommendations for improving that process.

Food recalls are critical to preventing people from consuming food that may be harmful. Prior OIG reviews have focused on FDA oversight of food recalls and inspections of food facilities.¹ The FDA Food Safety Modernization Act gave FDA new statutory authority, including the authority to order mandatory food recalls. Our recent audit, released at the end of December 2017, was aimed at determining whether FDA is fulfilling its responsibility to safeguard the Nation's food supply now that it has mandatory recall authority.²

This audit reviewed documentation for 30 recalls, including 23 Class I and 7 Class II recalls, which were judgmentally selected from the 1,557 food recalls reported to FDA between October 1, 2012, and May 4, 2015. In a Class I recall, there is a reasonable probability that the use of or exposure to the product could cause serious adverse health consequences or death. In a Class II recall, the use of or exposure to a product may cause temporary or medically reversible adverse health consequences or the probability of serious adverse health consequences or death is remote.

Because we selected a judgmental sample, the results are informative about deficiencies in FDA's food-recall oversight process but are not representative of the full population of FDA recalls. For the 30 food recalls we reviewed, we found that FDA's food-recall process was not always effective and efficient in ensuring the safety of the Nation's food supply. Specifically, we identified deficiencies in:

- FDA's oversight of recall initiation,
- FDA's monitoring of recalls, and
- the recall information captured and maintained in FDA's electronic Recall Enterprise System (RES).

¹ *Review of the Food and Drug Administration's Monitoring of Pet Food Recalls* (A-01-07-01503, August 2009). Available online at <https://oig.hhs.gov/oas/reports/region1/10701503.pdf>. *Review of the Food and Drug Administration's Monitoring of Imported Food Recalls* (A-01-09-01500, June 2011). Available online at <https://oig.hhs.gov/oas/reports/region10/10901500.pdf>. *Challenges Remain in FDA's Inspections of Domestic Food Facilities* (OEI-02-14-00420, September 2017). Available online at <https://oig.hhs.gov/oei/reports/oei-02-14-00420.pdf>.

² *The Food and Drug Administration's Food-Recall Process Did Not Always Ensure the Safety of the Nation's Food Supply* (A-01-16-01502, December 2017). Available online at <https://oig.hhs.gov/oas/reports/region1/11601502.pdf>.

My testimony today focuses on key aspects of these three findings and OIG's recommendations to FDA for improving its food-recall process. I will also highlight some of the actions that FDA officials told us that they took in response to the [Early Alert of Significant Preliminary Findings](#) (early alert) we issued in June 2016, in advance of the audit report. That early alert notified FDA that preliminary evidence suggested it did not have policies and procedures in place to ensure firms initiated food recalls promptly. According to FDA, our review and early alert were catalysts to major changes by FDA to strengthen its oversight of the food-recall process and its enforcement strategies. Although progress appears to have been made, more is needed to protect the Nation's food supply.

FDA's Oversight of Food Recalls

A recall is a firm's³ removal or correction of a marketed product that FDA considers to be in violation of the Federal Food, Drug and Cosmetic Act (FD&C Act) and against which FDA would initiate a legal action (e.g., seizure). When FDA learns about a potentially hazardous product, FDA may discuss the possibility of a recall with a firm without specifically requesting a recall. If the firm decides to recall the product, the firm's action is considered a voluntary recall. When a firm promptly initiates a voluntary product recall, FDA does not need to take further action to initiate the recall.

If a firm fails to voluntarily recall the product, or FDA determines that the recall is ineffective, FDA may take appropriate regulatory action. One action that FDA may consider is a mandatory recall. To use its mandatory recall authority, FDA must determine that there is a reasonable probability that the food is adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act and that it will cause serious adverse health consequences or death to humans or animals.⁴ FDA's mandatory recall procedures require it to complete a Health Hazard Evaluation (HHE), a tool used by FDA to evaluate the health hazard presented by a product, classify a recall, and assess a firm's recall strategy, before using its mandatory recall authority.⁵

Deficiencies in FDA's Oversight of Recall Initiation

Our review of FDA's oversight of firm-initiated recalls determined that FDA (1) could not always ensure that firms initiated recalls promptly and (2) did not always evaluate health hazards in a timely manner.

³ Firms are generally individuals or entities responsible for the product's manufacture and distribution.

⁴ Section 206 of the FSMA, P.L. No. 111-353 (enacted January 4, 2011), amending and adding section 423 to the Federal Food, Drug, and Cosmetic Act.

⁵ *Mandatory Food Recalls*, document number ORA-OEIO.055, version 1.1, dated December 27, 2012.

FDA Could Not Always Ensure That Firms Initiated Recalls Promptly

We found that FDA could not always ensure that firms initiated recalls promptly because FDA did not have adequate procedures to ensure that firms take prompt and effective action in initiating voluntary recalls.

For the 30 recalls that we reviewed, initiation of the recall occurred anywhere from 9 days before to 303 days after FDA learned that the product was potentially hazardous. Firms initiated these recalls an average of 57 days (with a median of 29 days) after FDA learned of the potential hazard. For example, one firm did not initiate a Class I recall of an adulterated dietary supplement until 303 days after receiving a warning letter from FDA stating that the product was adulterated. In that case, FDA and the firm disagreed about whether the supplement was lawful.

We found that FDA had not established risk-based internal timeframes for reaching certain milestones in the recall process, such as when FDA recall staff should request that firms voluntarily recall their products, which delayed it from taking further action in some recalls. For instance, when firms were reluctant to voluntarily initiate timely recalls, delays were more likely, and FDA's food-recall initiation process could not ensure the efficiency and effectiveness of food recalls. If FDA had established risk-based internal timeframes, it might have identified reluctant firms earlier in the food-recall process and taken appropriate action to protect public health.

FDA Did Not Always Evaluate Health Hazards in a Timely Manner

FDA uses an HHE to evaluate the health hazard presented by a product, classify a recall, and assess a firm's recall strategy. If a product is identical or similar to a previously classified recalled product, a precedent HHE may be used. FDA was unable to rely on a precedent HHE for 14 of the 30 recalls that we audited. In those 14 recalls, completion of the HHE ranged from 8 working days before FDA learned of a planned or in-progress recall to 209 working days after learning of a planned or in-progress recall. On average, FDA took 47 working days (with a median of 27 working days) to complete the HHEs associated with these 14 recalls.

We found that FDA did not complete some HHEs in a timely manner for several reasons. One reason was that FDA district staff located throughout the country did not always submit a recall alert about a planned or in-progress food recall to the RES within the timeframe outlined in its procedures. These recall alerts trigger the initiation of the HHE process. According to FDA's Regulatory Procedures Manual (RPM), a recall alert should be submitted as soon as possible, but preferably within 24 hours of the district learning of a planned or in-progress recall. For the 30 recalls that we audited, FDA district staff submitted the recall alert an average of 34 days after learning of a planned or in-progress recall.

Without a timely HHE, FDA could not send out to firms timely notification letters with FDA's formal written assessment of the firms' recall strategy and any suggested strategy revisions or request periodic status reports. Furthermore, without a timely HHE, FDA could not establish whether there was a reasonable probability that the product would cause serious adverse health consequences or death. Because FDA must establish this reasonable probability in order to

exercise its mandatory recall authority, FDA was not always in a position to determine whether it should order a mandatory food recall.

Key OIG Recommendations for Improving FDA's Oversight of Recall Initiation

To improve FDA's oversight of recall initiation, we recommended that FDA establish set timeframes for:

- discussing the possibility of a voluntary recall with a firm and
- initiating the use of its mandatory recall authority after it has made the determination that the legal standard for use of that authority has been met and a firm is not willing to voluntarily conduct a recall.

In addition, we recommended that FDA take several specific actions aimed at ensuring that HHEs are completed in a timely manner.

Deficiencies in FDA's Monitoring of Recalls

We identified several deficiencies in FDA's monitoring of firm-initiated recalls. Specifically, we found that FDA did not always (1) issue audit check assignments at the appropriate level, (2) complete audit checks in accordance with its procedures, and (3) collect timely and complete status reports from recalling firms.

FDA Did Not Always Issue Audit Check Assignments Consistent With the Level in the Proposed Audit Program

FDA monitoring district staff should establish a proposed audit program for monitoring a recall, which should include a timetable for reviewing the recall status and the level and type of audit checks. A recall "audit check" is a visit, telephone call, or letter (or a combination thereof) from an FDA district office to a consignee (anyone who received, purchased, or used the product being recalled) of a recalled product intended to verify that the consignee has been notified of the recall and has taken appropriate action. Depending on the audit check level, district offices should contact a certain percentage of consignees. FDA relies on the recalling firm to provide it with a distribution list of consignees that received the recalled product.

For 8 of the 27 recalls in our audit that required audit checks, FDA assigned fewer audit checks to its district offices than were called for by the audit check level in the proposed audit program. For example, in one Class I recall, the audit program proposed audit check Level A, which required the district offices to contact all 19 of the domestic consignees that received the recalled product, but FDA assigned audit checks for only 12 consignees.

FDA did not always assign audit checks consistent with the audit check levels in the audit plan because oversight of FDA's recall coordinators was insufficient, and the consignee distribution lists that FDA obtained from recalling firms were not always complete or accurate. Because

fewer audit checks were assigned than were required by the audit check level, there was an increased risk that consignees were not aware of the recall and recall instructions.

FDA Did Not Always Complete Audit Checks in Accordance With Its Procedures

We found that FDA did not always complete audit checks in accordance with timeframes set out in its procedures. As a result, FDA could not ensure that consignees took timely, appropriate action to remove harmful products from retail stores and from other points in the distribution chain. FDA's RPM states that FDA should normally assign audit checks to its district offices within 10 days of the firms' recall communication with consignees. The RPM states that the district office should consider the audit check assignments "high priority" and complete them within 10 days of assignment, if possible. In certain cases, FDA can use State agencies and third-party contractors to conduct audit checks.

For 5 of the 30 recalls in our audit, FDA determined that audit checks were not required. For 21 of the remaining 25 recalls that required audit checks, FDA did not complete the audit checks within the timeframes set out in its procedures. On average, the audit checks for these 21 recalls took 118 days (with a median of 69 days) to complete from the time of the firms' first recall communication. In one case, FDA did not complete the final audit check related to a Class I recall of a mislabeled product until 547 days after the firm first notified its consignees of the recall. Three of the 18 audit checks that FDA conducted for this recall were conducted more than 300 days after the firm issued the recall communication. This means that the mislabeled product was still on the shelves of three retail stores, and consumers remained at risk.

For all 21 recalls that did not have audit checks completed in a timely manner, we noted that FDA did not obtain assistance from State agencies or third-party contractors to help complete the audit checks. We also found that communication among the FDA staff conducting audit checks, recall coordinators, and district offices was not always effective in ensuring that audit checks were completed in a timely manner. In addition, none of FDA's data systems could be used to assist staff with tracking the status of audit checks. As a result, FDA could not ensure that consignees took timely, appropriate action and removed harmful products from the market.

FDA Did Not Always Collect Timely and Complete Status Reports From Recalling Firms

FDA should request periodic status reports from recalling firms so that FDA can monitor and assess the progress of a recall. Status reports should contain specific information, including the number and results of the firm's effectiveness checks. Effectiveness checks help firms and FDA verify that all known, affected consignees have received notification about a recall and have taken appropriate action.

FDA did not always collect timely status reports. For 11 of the 30 recalls covered by our audit, FDA either did not request or did not collect status reports. For the remaining 19 recalls, the average number of days for FDA to collect the first status report was 143 days (with a median of 122 days and range of 14 to 605 days) after the recall was initiated. In addition, when FDA collected status reports, they were not always complete. Of the 19 recalls in which FDA

obtained at least 1 status report, we found that status reports associated with 5 recalls did not contain complete effectiveness check information.

In one Class I recall that we audited, FDA did not officially request status reports from the recalling firm until 57 days after the recall was initiated and did not receive a status report until 605 days after the recall was initiated. There was not any evidence that FDA followed up with the firm about the status report in that timeframe, and, in addition to being untimely, the status report that FDA received did not contain information about the number and results of the firm's effectiveness checks.

FDA's procedures to collect timely and complete status reports from recalling firms were inadequate because they did not require staff to request status reports at the time a recall was initiated. In addition, FDA did not always follow up with firms when status reports were not provided, were provided late, or were incomplete. Without obtaining timely and complete status reports from a recalling firm, FDA could not adequately monitor the progress and effectiveness of the recall and assess whether additional action was necessary to protect the public.

Key OIG Recommendations for Improving FDA's Monitoring of Recalls

To improve FDA's monitoring of recalls, we recommended that FDA:

- take steps to ensure that audit checks are assigned at the level specified in the audit program and to ensure the completeness and accuracy of consignee distribution lists,
- take specific actions to help ensure that audit checks are completed in a timely manner,⁶ and
- implement procedures for requesting status reports at the initiation of a recall and follow up with firms that do not provide timely or complete status reports.

Deficiencies in FDA's Electronic Recall Enterprise System

Our review of FDA's electronic recall data system determined that FDA did not always (1) track key recall data and (2) maintain accurate recall data.

FDA Did Not Always Track Key Recall Data in RES

FDA uses RES, an electronic data system, to help manage recalls. RES also provides a central, searchable database that FDA can use to track information, generate reports about recall activities, and disseminate those reports.

We found that RES did not have a field for tracking all information necessary for FDA to effectively monitor recall activities and assess the timeliness of recalls. Specifically, RES did

⁶ Specifically, we recommended that FDA increase its use of third parties to perform audit checks, strengthen internal communication during the audit check process, and improve the ability of FDA information systems to track and monitor the status of audit checks.

not track the date that FDA learned a product was potentially hazardous. Therefore, FDA could not use RES to measure the amount of time between the date FDA learned that a product was potentially hazardous and the date a firm initiated a voluntary recall.

For example, in a Class I recall involving hazelnuts contaminated with *Salmonella*, FDA learned that the hazelnuts were potentially hazardous on December 2, 2012. The firm initiated the recall on May 2, 2013. However, because the RES did not have a field for the date that FDA first learned the product was potentially hazardous, FDA could not use the RES to calculate that it took the firm 151 days to initiate the recall after FDA first learned the product was potentially hazardous.

FDA staff documented the date that FDA learned a product was potentially hazardous only in the recall files. FDA officials stated that tracking this date for all recalls would be time consuming and difficult because the date may be located in different FDA systems or obtained from sources outside of FDA. However, without tracking this date in the RES, FDA could not effectively identify and respond to firms that were not prompt in recalling food products that FDA was aware presented a risk to public health.

FDA Did Not Always Maintain Accurate Recall Data

FDA did not always enter accurate recall initiation dates in the RES. The RES User Manual defines the recall initiation date as the “date that the recall action was initiated by a company.” However, for 11 of the 30 recalls we sampled, we determined that the recall initiation date in RES was off by an average of 16 days (with a median of 4 days). The inaccurate recall initiation dates ranged from 1 day before the initiation date inputted into the RES to 89 days after.

For example, in a Class I recall involving undeclared allergens in a dietary supplement, June 5, 2013, was entered as the recall initiation date. Based on a review of the recall file, however, we determined that recall was not initiated until the firm began notifying its consignees of the recall on September 2, 2013. The initiation date in the RES was incorrect by approximately 3 months (89 days).

FDA’s RES User Manual did not clearly define the term “recall initiation date” and, therefore, FDA staff input other dates into the RES. In the Class I recall discussed above, the recall coordinator explained that she entered the date the firm started discussing a possible recall as the recall initiation date. In addition, FDA did not have a data quality assurance process to help ensure that RES data were both accurate and complete.

Without an accurate recall initiation date documented in the RES, FDA could not use the RES to determine the length of time it took a firm to initiate a recall. As a result, FDA did not have assurance that the data in the RES were accurate and that the RES was reporting correct information.

Key OIG Recommendations for Improving the Completeness and Accuracy of FDA's Electronic Data Systems

To help ensure the completeness and accuracy of data in its data systems and give FDA staff involved in managing recalls access to information about key events, we recommended that FDA:

- consider adding to RES or another FDA system a field for the date FDA learns of a potentially hazardous product,
- establish performance measures for the amount of time between the date FDA learns of a potentially hazardous product and the date a firm initiates a voluntary recall,
- clarify the definition of “recall initiation date” in its policies and procedures and ensure a consistent understanding of “recall initiation date” among recall personnel, and
- develop and implement a data quality assurance process to ensure that the RES contains accurate information.

FDA Initiatives to Improve the Food-Recall Process

In response to our early alert, FDA informed us of several changes it had taken to improve the way it manages and oversees food recalls.

In April 2016, FDA established a team of senior FDA leaders charged with making decisions during the most challenging and high-risk food-recall cases. This team is called SCORE, which stands for Strategic Coordinated Oversight of Recall Execution. According to FDA, SCORE has reviewed and directed a large number of operations in the most difficult cases that FDA has faced since we issued our early alert, and has made a difference in ensuring that FDA acts quickly to investigate and reduce consumer exposure to potentially harmful foods on the market.

In September 2016, FDA's Office of Regulatory Affairs (ORA) designed and implemented a plan to audit ORA's recall program across all regulated product areas. ORA described the program as a “quality system recall audit plan” that provides for both “traditional auditing and continuous monitoring of the recall program.”

Finally, in December 2016, ORA completed a project charter that implemented a recall strategic plan. According to FDA, this plan is designed to identify strategic priorities that optimize FDA's policies and procedures regarding the recall of FDA-regulated products that pose a public health risk.

While we have not had the opportunity to assess the impact of these changes, we are encouraged by the proactive steps that FDA has taken to improve the food-recall process.

Conclusion

In its comments on our report, FDA agreed with our conclusion that it needs to help ensure that recalls are initiated promptly in all circumstances and said that it will consider the results of our review as it continues to operate the SCORE initiative. Among other things, FDA stated that it is initiating a new quality system audit process and a plan to provide early notice to the public and more guidance to staff. We appreciate the steps FDA has taken as well as the steps it plans to take to address the vulnerabilities we identified during our audit.

We also appreciate the Subcommittee's interest in our audit and thank you for the opportunity to testify on ways for FDA to improve its oversight of the food-recall process. Conducting audits, evaluations, and inspections aimed at food safety is a priority for OIG and remains key to our mission of protecting the health and safety of the American people. Since FY 2015, OIG has increased its efforts to oversee FDA by (1) assessing FDA's implementation of new authorities, (2) monitoring existing FDA programs, (3) reviewing FDA's readiness to address new threats to public health and safety, and (4) investigating FDA's administration and fraud, waste, and abuse. OIG will continue to work with FDA and Congress to help ensure the safety of the Nation's food supply.

I look forward to answering your questions.