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SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
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U.S. HOUSE OF REPRESENTATIVES

“SAFETY OF THE U.S. FOOD SUPPLY: CONTINUING CONCERNS OVER THE
FOOD AND DRUG ADMINISTRATION'S FOOD RECALL PROCESS”

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INTRODUCTION

Good morning, Chairman Harper, Ranking Member DeGette, and members of the Subcommittee. I am Douglas Stearn, director of the Office of Enforcement and Import Operations in the Office of Regulatory Affairs of the U.S. Food and Drug Administration (FDA or the Agency) within the Department of Health and Human Services. Currently, I am serving as the acting deputy director for regulatory affairs at the Center for Food Safety and Applied Nutrition within FDA. I am also the co-chair of the Strategic Coordinated Oversight of Recall Execution (SCORE).

We appreciate the opportunity to provide you with information about how we oversee recalls of FDA-regulated products that can harm consumers. FDA is committed to continuously improving our policies and practices to ensure that food recalls are initiated, overseen, and completed promptly and effectively to best protect consumers. In this regard, we appreciate the Office of Inspector General's (OIG's) focus on this subject and would like to thank the committee for the opportunity to report on major changes FDA has made in response to OIG's investigation.

When we learn about a food in the marketplace that may be unsafe, we must act quickly to keep people from getting sick or being harmed. If foodborne illness has already occurred, we also must act quickly to keep more people from becoming ill. FDA has authority to act in a variety of ways, but often the fastest and most efficient way to ensure unsafe foods are recalled quickly is by working directly with the involved companies while simultaneously providing the public with timely, accurate information that they can act on. Making sure FDA has effective recall practices in place, and that we take immediate action to address unsafe foods, are high priorities of the Agency. Our recall authorities – and how we deploy them – are a cornerstone of our vital consumer protection mission.

ROLES OF INDUSTRY AND FDA IN CONDUCTING RECALLS

FDA has wide-ranging oversight responsibilities. In the foods area, FDA is responsible for inspecting more than 88,000 domestic registered food facilities that manufacture, process, pack, or hold food. In addition to domestic food facilities, FDA is also responsible for ensuring the safety of food imported from the more than 212,000 registered foreign food facilities, producing more than 12 million food commodity import occurrences into the United States in fiscal year 2016. In addition to inspections of those food facilities, FDA is responsible for overseeing the industry's recall of food products that present a risk of injury or gross deception or are otherwise violative. In recent years, FDA has overseen thousands of food recalls annually. In FY 2017 alone, FDA oversaw more than 3,600 product recalls.

Until the FDA Food Safety Modernization Act (FSMA) was signed into law in 2011, with the exception of infant formula, food recalls were defined as voluntary actions that were dependent on manufacturers and distributors to effectively discharge their recall responsibilities. Recalls were considered exclusively as voluntary alternatives to court actions against non-compliant firms that FDA might otherwise initiate. FDA's role in this voluntary process was to monitor recalls and assess the adequacy of firms' efforts so that the Agency could take additional action when necessary. Subpart C of Part 7 of FDA's regulations (Title 21, Code of Federal Regulations, Sections 7.40-59) governs the voluntary product recalls, and FDA also has published guidance for recalling firms (see <https://www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM592851.pdf>). FDA's guidance on voluntary recalls describes actions that FDA and the industry can take to carry out their respective recall responsibilities. The underlying premise of this guidance is that firms producing and marketing FDA-regulated products assume a responsibility to timely remove violative products from the marketplace when removal is necessary to protect the public health.

Under FSMA, FDA has authority to mandate a recall of a food product when FDA determines that there is a reasonable probability that an article of food is adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) and/or is misbranded under section 403(w) of the FD&C Act and where there is a reasonable probability that the use of or exposure to such food would cause serious adverse health consequences or death to humans or animals. In May 2015, FDA issued guidance explaining the mandatory recall provision. (See <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm445428.htm>.) We believe FDA's mandatory recall authority has played an important role in motivating firms to initiate voluntary recalls. When the firm does not take the appropriate actions, FDA can initiate use of the mandatory recall authority, which it has done on two occasions.

The cooperation and transparency of industry are critical in ensuring that violative products are promptly and effectively removed from the marketplace. FDA urges recalling firms to notify the Agency as soon as they determine a recall is appropriate. In addition, registered food facilities are required to report to FDA through the Reportable Food Registry when there is a reasonable probability that the use of, or exposure to, an article of food (applies to all FDA-regulated categories of food and feed, except dietary supplements and infant formula) will cause serious adverse health consequences or death to humans or animals. In many other cases, inspectional findings, sampling results, or other information in the Agency's possession leads to discussions with firms that can result in a firm's decision to recall a product. FDA typically asks firms to provide information to the Agency about the recall, including the reason for the recall, how the problem occurred, the extent of the problem, how and when the firm discovered the problem, where the product was distributed, and any consumer or supplier complaints.

Recalling firms and FDA generally work collaboratively to develop a recall strategy or to review the firm's existing recall strategy. The recall strategy allows FDA to determine the steps it must take to address the specific circumstances, which may include making certain that all products that need to be recalled are, in fact, recalled; helping to locate the product subject to the recall; assisting to identify the cause of the problem; and checking associated firms or products to determine if the problem could be more widespread. FDA uses information it learns during recalls to help prevent future problems and to identify similar problems if they arise in the future.

Throughout the course of the recall, it is the firm's responsibility to determine whether the recall is progressing satisfactorily by performing effectiveness checks. These checks help to verify that all known, affected consignees have received notification about a recall and have taken appropriate action. At the same time, FDA conducts "audit checks" to assess the effectiveness of a firm's recall efforts.

Even though the firm recalling the product may publicize its recall, FDA will further publicize a recall when it believes the public needs to be alerted about a serious hazard. Notifying the news media is an effective way to inform large numbers of people that a widely distributed product has been recalled. FDA also provides notifications about all recalls of FDA-regulated products in its weekly FDA Enforcement Report. (See <https://www.accessdata.fda.gov/scripts/ires/index.cfm>.)

FDA WORK WITH FIRMS DURING RECALLS

FDA is committed to working with recalling firms whenever possible to facilitate the orderly and prompt removal of a violative product from the marketplace, and has a variety of mechanisms in place to achieve this goal. FDA has field recall coordinators located throughout the country to act as the point of contact for a recalling firm and to assist firms with a recall. The recall coordinators provide a recalling firm with information about the recall process and are available to work closely with the firm throughout the course of the recall. For example, recall coordinators assist the firm in determining an appropriate recall strategy, review the recalling firm's notification letter to customers affected by the recall, and coordinate the appropriate destruction, reconditioning, or disposition of the recalled product.

In addition, FDA has developed "model" press releases available for use by recalling firms that need to issue press releases to inform the public about a recall. These model press releases help ensure that all appropriate information about the recalled product is accurately and appropriately conveyed to the public. Further, FDA encourages recalling firms to consult with their local recall coordinators before issuing press releases.

To assist firms in communicating their recall actions, and to help ensure that the public is informed, FDA posts firms' press releases on the Agency's website. FDA will also post photos of the recalled food product if provided by the firm. The use of product photographs for food recalls has also proven successful and useful to consumers.

FDA'S COMMITMENT TO IMPROVING RECALL PROCESSES, DISCLOSURE, AND EXECUTION

The recent OIG review of a judgmental sample of thirty food recalls initiated between 2012 and 2015 found some unacceptable delays in the removal of food from the market. As noted in the report, these were among the most complex recalls FDA deals with, and these recalls presented unique challenges, including: criminal behavior from a firm that hid critical information from the Agency; using new technology that links information from outbreaks to facilities; and putting information together from disparate sources to determine the appropriate expansion of a recall once an initial lot of contaminated food has been recalled. These are the types of challenges we are committed to addressing. Since the time period examined in this report, we have taken – and continue to take – OIG's recommendations seriously, and FDA leadership worked quickly to put in place measures to address the proposals that OIG outlined.

One of the most significant steps FDA has taken was in April 2016, by establishing a team of senior leaders charged with reviewing complex or unusual food safety situations and determining the proper action to address the problem if it is not clear. The team meets at least weekly and makes recommendations about what actions to take and how to make sure they occur.

This team of senior leaders, called SCORE, which stands for "Strategic Coordinated Oversight of Recall Execution," has made a remarkable difference in addressing more complicated, challenging, or unusual incidents. SCORE has been involved in various disparate cases including lead contamination of a dietary supplement, *Salmonella* contamination of powdered milk, *E. coli* O157:H7 in soy nut butter, and *Listeria* in hummus, soft cheese, and smoked fish. In addition to facilitating recalls and import alerts for the detention of products entering the United States, SCORE initiated or helped to expedite the process for suspending the registration of two food facilities, actions that block the facilities' ability to distribute food to the marketplace.

In addition to the establishment of SCORE, FDA has put in place several additional procedural and policy changes. Last year, after a comprehensive review of our recall process, we developed a new strategic plan that outlines actions to improve FDA's recall management. The plan helps to standardize how FDA assesses a company's recall efforts, establishes monitoring of the

Agency's recall activities, provides additional training and guidance to our staff involved in recall efforts so they can properly monitor and assess the effectiveness of a recall, and increases the timeliness and amount of recall information provided to the public.

The changes FDA has completed regarding its internal procedures since the OIG investigation include the following:

- Established a monthly monitoring system that indicates to field personnel when a recall activity appears to be slower.
- Completed a baseline audit of recalls in each district indicating the timeliness of each step throughout the recall process that provides a basis for field management to address untimely performance or challenges.
- Revised procedures to clarify when FDA may informally recommend that a firm cease distribution of, or recall a violative product to improve efficiency in processing cases. (*See Regulatory Procedures Manual (RPM) 7-5-1.*)
- Updated FDA's Recall Audit Check Report and its instructions to ensure better documentation of recall audit checks, which is necessary to document the receipt of recalled product and notification of the recall, as well as the appropriate disposal of the product as instructed in the recall notification. (*See IOM Exhibit 7-3.*)
- Expanded our third-party recall audit check contract to increase the number of recall audit checks performed.
- Added fields in the Recall Enterprise System, FDA's internal recall database, to allow for more complete evaluation of recall time lines, including the Recall Determination Date, the Recall Audit Check Assignment Date, and the Recall Audit Check Completion Date to provide a greater ability to monitor open recalls to ensure that the recall is completed and terminated more promptly.
- Created a central location and enhanced communications to foreign firms and governments to ensure that FDA initiates the oversight of recalls originally initiated by foreign suppliers.
- Created a set of best practice recommendations for States to facilitate communication and coordination of recall activities in response to a Class I recall or a recall related to an outbreak.

In addition to the list above, the Agency anticipates implementing additional revisions, procedural enhancements, and new policies that will continue to improve how we protect the public through the recall process and in our communications to consumers.

FDA has also improved its recall classification process, speeding it up by enhancing our tracking of individual cases throughout the classification process, cross-training employees, and utilizing cross-trained employees during surge periods. As a result of a change that began in fiscal year 2017, FDA now averages 13-15 days to classify food and cosmetic recalls from the recall recommendation, down from 79 days only a year earlier. FDA intends to continue efforts to further shorten this time period.

IMPLICATIONS FOR FOOD RECALL PROCESSES FROM OTHER FDA CHANGE INITIATIVES

FDA is also currently pursuing major initiatives that have implications for how the Agency oversees its recall functions into the future. Over the last several years, the Agency has been focused on finalizing and implementing FSMA, the most sweeping reform of food safety laws in almost 70 years, which shifts the focus of the U.S. food safety system from responding to contamination to preventing it. One of the preventative measures FSMA addresses concerns how firms conduct recalls. As part of the FSMA regulation on preventive controls for human food, where a hazard analysis identifies a need for a preventive control, the facility must have a written recall plan that includes procedures to notify consignees, to notify the public when necessary, to conduct effectiveness checks, and to appropriately dispose of recalled product. In addition, FDA field operations in the Office of Regulatory Affairs have recently undergone a reorganization to meet the challenges of keeping pace with the scientific innovation, globalization, and increasing breadth and complexity of regulated products, as well as new legal authorities. With ORA's program alignment, FDA field staff now specialize in specific FDA-regulated product areas. Among the FDA field staff who have become specialized are the recall coordinators responsible for working with firms on food recalls, as noted above. These field staff are developing deeper knowledge of FDA's food safety standards, food inspections, and regulatory tools applicable to food, and a closer relationship with the Center for Food Safety and Applied Nutrition.

CONCLUSION

Thank you for the opportunity to discuss FDA's recall process. I would be happy to answer any questions you may have.