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MEMORANDUM

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Date: January 11, 2017

Re: FDA Responds to HHS Office of Inspector General Report Identifying Flaws in FDA's Food Recall Processes

In response to a recent report by the Department of Health and Human Services (HHS) Office of Inspector General (OIG), Food and Drug Administration (FDA) Commissioner Scott Gottlieb, M.D., announced that FDA will be issuing guidance on recall communications within the next six months. Commissioner Gottlieb's announcement followed an OIG report that identified several shortcomings in FDA's initiation and oversight of food recalls.

OIG had issued an "early alert" in June 2016 notifying FDA of its preliminary finding that FDA lacks policies and procedures to ensure that firms or responsible parties initiate food recalls promptly. The complete report issued in December includes additional findings concerning issues such as the timeliness of FDA's evaluation of health hazards and audit checks, as well as actions FDA has taken in response to the early alert. 1/ This memorandum summarizes the report's findings and the policy initiatives Commissioner Gottlieb has announced in response to it.

Background

In June 2016, OIG issued an early alert to FDA stating that FDA does not have an efficient and effective food recall initiation process. 2/ To address this issue, OIG suggested FDA update its policies to instruct recall staff to establish set timeframes for (1) FDA to request that firms voluntarily recall their products and (2) for firms to initiate voluntary food recalls. The early alert was based on OIG's review of 30 voluntary recalls OIG selected from the 1,557 recalls reported to FDA between October 1, 2012 and May 4, 2015.

OIG conducted the recall audits as a follow up to a report it issued in 2011, *Review of the Food and Drug Administration's Monitoring of Imported Food Recalls*, which found that FDA's food recall program was inadequate because, at the time of its review, FDA did not have the authority to require

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1/ *See* Office of Inspector General, Department of Health and Human Services, "The Food and Drug Administration's Food-Recall Process Did Not Always Ensure the Safety of the Nation's Food Supply," (Dec. 2017), available at https://oig.hhs.gov/oas/reports/region1/11601502.pdf.
2/ *See* HL Memo – HHS Office of Inspector General Finds Flaws in FDA's Food Recall Initiation Process (June 14, 2016).

firms to recall certain foods and FDA did not always follow its own procedures. The FDA Food Safety Modernization Act (FSMA) granted FDA the authority to mandate a recall under certain conditions, 3/ and OIG recommended FDA consider OIG's 2011 findings when it implemented FSMA.

OIG's Report Findings

OIG's report includes additional findings based on its continued review of the 30 voluntary recalls. The report identifies shortcomings in FDA's oversight of recall initiation, monitoring of recalls, and the recall information FDA captures and maintains in its recall data system, the Recall Enterprise System (RES). In addition to its previous finding that FDA did not always initiate recalls promptly, the report identifies the following issues.

1. **Health Hazard Evaluation:** FDA did not always evaluate health hazards in a timely manner, which would limit FDA's ability to use its mandatory recall authority in certain Class I recalls. FDA explained that delays in evaluating health hazards were due to difficulties in obtaining the information necessary to make decisions about the seriousness of the health hazard presented by the product, among other reasons.

2. **Audit Checks:** FDA did not always issue audit check assignments at the appropriate level, and audit checks were not always completed in accordance with FDA's procedures. According to OIG, FDA's monitoring of recalls was not always adequate because FDA staff had insufficient oversight to ensure that the assignment was at the right level, and FDA obtained incomplete or inaccurate consignee information from firms initiating recalls.

3. **Status Reports:** FDA did not always collect timely and complete status reports from firms that have issued recalls because FDA's procedures did not require staff to request status reports at the time the recall was initiated.

4. **Data Collection:** FDA did not always track key recall data in RES, nor maintain accurate recall data in RES. The RES contained deficient recall information because it did not track all information necessary for FDA to effectively monitor recall activities and assess the timeliness of recalls.

The report states that in response to OIG's early alert, FDA established its Strategic Coordinated Oversight of Recall Execution (SCORE) initiative, a team of senior leaders that makes decisions during the most challenging high-risk food recall cases. FDA also implemented a plan to audit the Office of Regulatory Affairs' (ORA's) recall program, and ORA completed a project charter implementing a recall strategic plan to identify strategic priorities to optimize FDA's policies and procedures regarding recalls.

The report identifies a number of recommendations for improving FDA's recall processes, including using SCORE to establish set timeframes for FDA to discuss the possibility of a voluntary recall with a firm and to initiate use of FDA's mandatory recall authority after FDA determines the legal standard for use of the authority has been met and the firm is not willing to conduct a recall voluntarily. Other recommendations include developing procedures to determine whether reconciliation of distribution lists to shipping records is necessary to ensure FDA uses complete and accurate distribution lists when assigning audit checks, increasing the use of third-party audit checks, and developing a data quality assurance process to ensure the RES contains accurate information.

3/ Federal Food, Drug, and Cosmetic Act § 423. Before issuing a mandatory recall order, FDA must provide the firm with an opportunity to voluntarily recall the product.

FDA Commissioner Gottlieb's Response

FDA Commissioner Gottlieb issued a public statement following release of the report, noting FDA's work since OIG issued the early alert in 2016 and identifying additional steps FDA has planned. 4/ In particular, Commissioner Gottlieb said FDA intends "to do even more to make sure that consumers have the information they need to avoid hazardous products that are the subject of recalls, or to seek assistance if they may have been exposed to a recalled food product." This includes new guidance on recall communications, which FDA plans to release in the first half of 2018. FDA also is examining in what situations it can help consumers get information about the stores and food service locations that may have sold or distributed recalled food, and what company may have supplied the product. Commissioner Gottlieb said that if FDA is able to disclose this information, consumers would have an easier time knowing if they might have, or have been, exposed to a recalled product.

Note that, due to the publicity this OIG report has received in the media and elsewhere, food companies initiating recalls in the coming months may experience an even greater sense of urgency from FDA recall coordinators and other FDA staff than companies may have experienced in the past.

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We will continue to monitor developments related to FDA's recall policies. Please contact us if you would like further information on this issue.

4/ "Statement from FDA Commissioner Scott Gottlieb, M.D. on efforts to support more efficient and effective food recalls," (Dec. 26, 2017), available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm590423.htm.