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MEMORANDUM

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Re: **OIG Report Scrutinizes FDA's Domestic Food Facility Inspection Program**

The Department of Health and Human Services' Office of Inspector General (OIG) issued a report last week detailing the results of its review the Food and Drug Administration's (FDA's) inspection of domestic food facilities, as well as its advisory and enforcement actions taken in response to significant inspection violations. 1/ The key takeaway from the report is that FDA should do more to ensure the food supply is safe by taking "swift and effective action" to ensure facilities promptly correct problems identified during inspections. This memorandum summarizes the OIG's key findings and recommendations and also discusses how the report may affect facility inspections and subsequent agency actions in the future.

Key Findings

The OIG's report includes five primary findings related to FDA's pace of domestic food facility inspections, the rate of follow-up inspections, FDA actions to ensure facilities take corrective action, and the timeliness of FDA's response actions.

- **Finding 1: FDA is on track to meet the initial inspection timeframes FSMA mandates, but challenges remain to meet those timeframes going forward.**

The FDA Food Safety Modernization Act (FSMA) mandated that FDA increase the frequency of its inspections based on risk. The law required FDA to inspect high-risk facilities at least once during the initial 5-year period (from 2011 to 2015), and then at least once every 3 years for subsequent cycles. For non-high-risk facilities, FDA was required to conduct an inspection at least once during the initial 7-year cycle (from 2011 to 2017), and then at least once every 5 years for subsequent cycles.

For the initial cycle, FDA identified 21,086 high-risk facilities, and by the end of 2015 FDA had inspected or attempted to inspect all but 9 of them. Of the 61,010 non-high-risk facilities, FDA had inspected or attempted to inspect 40,623, with 2 years remaining in the inspection cycle. The OIG concluded that FDA is on track to inspect the remaining facilities by the end of 2017.

However, the OIG identified several factors that may prevent FDA from meeting the timeframes

1/ Challenges Remain in FDA's Inspections of Domestic Food Facilities (Sept. 2017), *available at* https://oig.hhs.gov/oei/reports/oei-02-14-00420.pdf.

going forward:

- The shorter timeframes for future inspection cycles likely will pose a challenge for FDA's future inspections of non-high-risk facilities. To meet the shorter time period, FDA would have to increase its previous pace of an average of 8,125 inspections per year from 2011 to 2015 to at least 12,000 per year.

- Inaccurate information, leading to attempted inspections of closed or non-operational facilities, consumes too many of FDA's inspection resources. More than 25% of facilities FDA counted toward meeting its inspection mandates for the initial cycles were out of business or not in operation at the time of the inspection. In its response to the report, however, FDA said it expects its data to improve and for there to be fewer attempted inspections over time.

- FDA lacks a policy to reschedule inspections on a timely basis if the inspection is attempted but not executed, such as may be the case for a seasonal operation or facility that is temporarily closed. Consequently, some facilities FDA attempted to inspect during its initial cycle still need to be inspected. FDA said that going forward it will immediately establish a date to reschedule such an inspection.

- **Finding 2: Although FDA is on track to meet the FSMA inspection mandates, this did not result in an increase in the number of facilities inspected.**

The number of facilities FDA has actually inspected each year (not including the number of facilities it attempted to inspect) has decreased from around 17,000 facilities in 2004 to 16,000 facilities in 2015—though FDA inspected a peak number of facilities, 19,000, in 2011. In addition, as the number of facilities inspected has decreased, the number of facilities within FDA's jurisdiction has increased. Consequently, the proportion of facilities inspected by FDA in a given year decreased from 29 percent in 2004 to 19 percent in 2015. Thus, it appears the initial FSMA inspection timeframes merely codified pre-existing agency practices. It also suggests that FDA may need added resources to meet the more aggressive timeframes moving forward.

- **Finding 3: FDA did not always take action to ensure facilities corrected significant inspection violations.**

According to the OIG, when FDA uncovers a significant inspection violation and classifies the inspection as "official action indicated" (OAI), then an advisory action (e.g., warning letter, untitled letter, regulatory meeting) or enforcement action (e.g., seizure, injunction, prosecution) is warranted. FDA took no advisory or enforcement action after 22% of the inspections with significant inspection violations from 2011 to 2015. According to the OIG, if FDA takes no action in these cases, facilities may not correct the violations, which undermines FDA's efforts to ensure a safe food supply.

- **Finding 4: When FDA took action, it typically relied on facilities to correct significant violations voluntarily. FDA's actions were not always timely, nor did they always result in correction of the violations.**

FDA responded with an advisory action (e.g., warning letter, untitled letter, or regulatory meeting) for 73% of significant inspection violations, judicial action (e.g., seizure, injunction) in 4%, and administrative action (e.g., detention of food, suspension of facility registration) in 1%. The OIG observed that FDA rarely used its expanded enforcement authorities under FSMA. Between 2011 and 2015, FDA exercised its authority to issue an administrative detention order in only 5 instances, suspend facility registration in 2 instances, and never initiated a mandatory recall in response to significant inspection violations.

The OIG reported that FDA has a goal of issuing all warning letters within 4 months of inspecting a facility or receiving a positive test sample. Between 2011 and 2015, however, FDA issued nearly half of all warning letters after this timeframe. FDA issued 20% of warning letters after more than 6 months and 2% after more than a year following an inspection. On average, FDA initiated judicial action within 6.7 months, advisory action within 4.5 months, and administrative action within 2.8 months.

The OIG also found that when FDA relied on voluntary compliance by taking an advisory action, facilities did not always correct the problems. Of the 766 facilities that received advisory actions for which FDA conducted a follow-up inspection, around 20% were cited as having significant inspection violations resulting in a second OAI classification. In around 75% of these facilities, FDA found violations identical to those in the previous inspection.

- **Finding 5: FDA did not consistently conduct timely follow-up inspections to confirm facilities had corrected significant inspection violations.**

For 48% of significant inspection violations between 2011 and 2015, FDA did not conduct a follow-up inspection within a year of the initial inspection. For 17% of significant inspection violations, FDA did not conduct any follow-up inspection. FDA followed up on 40% of serious inspection violations within 6 months to a year, and 11% within 6 months.

OIG Recommendations and FDA's Response

The OIG report concludes that its findings "show that FDA did not always take swift and effective action to ensure that significant violations were corrected; more needs to be done to protect our food supply." According to the OIG, if FDA does not routinely inspect food facilities and ensure that violations are remedied, it cannot ensure facilities are complying with applicable laws and regulations or that food handled by facilities is safe. The OIG report included 4 recommendations for FDA to improve its inspection and follow-up practices. FDA agreed with each of the recommendations, and has already taken action in response to some of them.

- **Recommendation 1: FDA should improve how it handles attempted inspections to ensure better use of resources.**

The OIG recommends that FDA improve the accuracy of its facility information, including removing facilities that are out of business from its list of facilities to inspect. The OIG also recommends that FDA adopt a policy for rescheduling attempted inspections. As indicated above, FDA has since developed a policy to immediately reschedule inspections for facilities that temporarily are not operating.

- **Recommendation 2: FDA should take appropriate action against all facilities with significant inspection violations.**

In a 2010 OIG review of FDA's inspection program, the OIG recommended that FDA take appropriate action against facilities with significant inspections. In this recent report, the OIG found that FDA had not yet implemented this recommendation. OIG continues to recommend that FDA take the most effective action to achieve compliance and to take administrative or judicial actions against facilities that do not voluntarily comply. The OIG also suggests FDA use its new enforcement tools under FSMA more frequently.

In its response to the OIG, FDA reported that it has developed a report that can display OAI inspection classifications and resulting regulatory action(s) and activities that were taken. FDA said

the report can be used to track compliance activities more efficiently.

- **Recommendation 3: FDA should improve the timeliness of its actions, including warning letters, so companies do not continue to operate under harmful conditions.**

According to the OIG, facilities may continue to operate under conditions that may threaten public health if FDA does not take action in a timely manner. Accordingly, the OIG recommends that FDA initiate regulatory actions promptly in response to facilities with significant inspection violations found during OAI classified inspections, including issuing warning letters in a timely manner.

In response, FDA explained that it focuses its efforts on those scenarios that may involve an immediate risk to public health. FDA reported that it has taken steps to facilitate timely advisory actions, including allowing district offices to initiate advisory actions without prior review by the Center or the Office of Chief Counsel for acidified food and juice HACCP violations. 2/

In response to OIG's draft report, FDA conducted an assessment of the warning letters issued more than 6 months after an initial inspection and found that more than 65% involved dietary supplement facilities. In addition, all but a few warning letters issued more than a year after the inspection similarly involved dietary supplements. FDA explained that it anticipates its previous action to create the Office of Dietary Supplement Programs (ODSP), elevating the program from its previous status as a division under the Office of Nutrition Labeling and Dietary Supplements, will raise the profile of dietary supplements in the agency and allow ODSP to better compete for government resources to better regulate the supplement industry.

FDA also noted that the warning letters issued more than a year after the initial inspection included examples of misbranded food or food or dietary supplements marketed with disease claims. FDA said that some of the violations, though serious, represent less immediate public health risk compared to violations involving the safety of food production, bacterial contamination, or allergen declaration.

- **Recommendation 4: FDA should conduct timely follow-up inspections to ensure facilities correct significant inspection violations.**

In its 2010 report, the OIG recommended that FDA ensure all facilities correct significant inspection violations found during an OAI classified inspection. The recent report reiterates this recommendation, and also suggests that FDA conduct follow-up inspections in a timely manner to verify facilities have remedied all violations.

FDA responded that it currently is developing a system that, once fully developed and implemented, will track activities or information concerning each specific inspection observation or violation to ensure they are corrected for all facilities that receive an OAI classification. FDA also noted that it has created a multi-programmatic oversight group, Strategic Coordinated Oversight of Recall Execution (SCORE), to increase the timely response to violative inspections that warrant follow-up by FDA.

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As FDA works to implement the OIG's recommendations, companies with significant inspection violations may expect to see swifter advisory or enforcement action from FDA. FDA also could potentially increase its use of its expanded enforcement powers such as administrative detention orders or suspension of registration. However, we expect FDA will continue to focus its efforts on those violations that pose an immediate public health safety risk.

2/ FDA previously granted district offices similar authority for advisory actions involving seafood HACCP violations in 2011.

We will continue to monitor FDA's inspection and enforcement actions. Please contact us if you have any questions regarding this or any other matter.