REPORT HIGHLIGHTS

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The Food and Drug Administration's Inspection and Recall Process Should Be Improved To Ensure the Safety of the Infant Formula Supply

Why OIG Did This Audit

- The Food and Drug Administration (FDA) warned consumers not to use certain powdered infant formula products from Abbott Laboratories' (Abbott's) Sturgis, Michigan, production facility (Abbott facility) in February 2022.
- Abbott voluntarily ceased production at the facility and initiated a voluntary recall of certain infant formula products while FDA conducted an inspection of the Abbott facility prompted by several consumer complaints and a whistleblower complaint that alleged a series of safety concerns at the facility.
- In prior work, OIG identified problems with FDA's inspections of domestic food facilities and its oversight of food recalls. We initiated this audit to examine FDA's oversight of infant formula.

What OIG Found

FDA had inadequate policies and procedures or lacked policies and procedures to identify risks to infant formula and respond effectively through its complaint, inspection, and recall processes. For example, FDA had not developed an organizational structure or assigned responsibilities to handle whistleblower complaints in an efficient and effective manner and took more than 15 months to address a February 2021 Abbott facility whistleblower complaint. In addition, FDA did not escalate an October 2021 whistleblower complaint to senior leadership, resulting in a nearly 4-month delay before senior leadership was aware of the complaint. We also found that FDA did not have policies and procedures to establish timeframes for the initiation of mission-critical inspections, which contributed to one inspection being initiated 102 days after a whistleblower complaint was received. Further, FDA did not have sufficient policies and procedures on how to initiate an infant formula recall under its FDA-required recall authority.

What OIG Recommends

We made nine recommendations to FDA, including that it: (1) maintain the National Consumer Complaint Coordinator's (NCCC's) continuity of operations by cross-training staff on whistleblower policies and procedures and NCCC duties, (2) develop and implement policies and procedures requiring periodic reporting to senior leadership on the status of open whistleblower complaints, (3) develop policies and procedures that FDA can use during future public health emergencies to identify how and when it is necessary to conduct mission-critical inspections and ensure that they are conducted in a timely manner, and (4) design and implement policies and procedures specific to the use of its FDA-required infant formula recall authority. The full recommendations are in the report. FDA concurred with all nine of our recommendations.