Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

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

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Office of Inspector General

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

REPORT HIGHLIGHTS

June 2024 | A-01-22-01502

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.

TABLE OF CONTENTS

ACRONYM LIST

CAERS	CFSAN Adverse Event Reporting System
CDC	Centers for Disease Control and Prevention
CFSAN	Center for Food Safety and Applied Nutrition
DOL	Department of Labor
EIR	establishment inspection report
FACTS	Field Accomplishments & Compliance Tracking System
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
FMD	field management directive
FY	fiscal year
GAO	Government Accountability Office
HHS	Department of Health and Human Services
IOM	*Investigations Operations Manual*
NCCC	National Consumer Complaint Coordinator
NCR	nonconformance report
OEO	Office of Emergency Operations
OFPR	Office of Food Policy and Response
OIG	Office of Inspector General
ORA	Office of Regulatory Affairs
QFC	quality factor checklist
RPM	*Regulatory Procedures Manual*
SOP	standard operating procedure
USDA	U.S. Department of Agriculture
VAI	Voluntary Action Indicated
WIC	Special Supplemental Nutrition Program for Women, Infants, and Children

INTRODUCTION

WHY WE DID THIS AUDIT

On February 17, 2022, 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). Abbott voluntarily ceased production at the facility and initiated a voluntary recall of certain powdered infant formula products, including Similac, Alimentum, and EleCare. This voluntary recall occurred during an ongoing inspection that FDA initiated of the Abbott facility on January 31, 2022. The inspection was prompted by a number of consumer complaints of infant illnesses related to *Cronobacter sakazakii* (*Cronobacter*) and a whistleblower's allegations of safety concerns at the facility.[1] According to Abbott, prior to the February recall, Abbott accounted for approximately 40 percent of the United States' infant formula market. Approximately 40 percent of Abbott's total U.S. formula supply was made at the Abbott facility.[2] A production shutdown and voluntary recall of this magnitude was concerning because, according to FDA, more than 3.5 million babies are born in the United States each year, many of whom rely on infant formula at some point as their sole source of nutrition.

Congress has expressed concerns about, and the media has reported on, whether FDA took prompt, appropriate, and effective action leading up to the Abbott powdered infant formula recall. In our December 2017 audit, we previously identified vulnerabilities in FDA's oversight of food recalls, including a finding that FDA did not ensure that manufactures initiated recalls promptly.[3] This resulted in continued risk to people of serious illness or death.[4] Our September 2017 review also identified challenges related to FDA's domestic food facility

[1] According to FDA's website, *Cronobacter sakazakii*, formerly *Enterobacter sakazakii*, is a germ or pathogenic bacteria that can cause illness primarily among infants younger than 2 months old and those who are born premature, have weakened immune systems, or are of low birthweight. *Cronobacter* is naturally found in the environment and is particularly good at surviving in low-moisture, dry foods, such as powdered infant formula/milk, herbal teas, and starches. *Cronobacter* illnesses have been associated with the consumption of powdered infant formula. Although *Cronobacter* infections are rare, they can be deadly for young infants and for people with weakened immune systems.

[2] United States House of Representatives, Subcommittee on Oversight and Investigations, "Formula Safety and Supply: Protecting the Health of America's Babies" (lines 4472 to 4480), May 25, 2022. Available online at https://www.congress.gov/117/meeting/house/114821/documents/HHRG-117-IF02-Transcript-20220525.pdf. Accessed on May 20, 2024.

[3] Recall means a firm's removal or correction of a marketed product that FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action (e.g., seizure). We will refer to firms as "manufactures" throughout the report.

[4] *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) Dec. 22, 2017.

inspection program.[5] Accordingly, we initiated this audit to examine FDA's oversight of infant formula.

OBJECTIVE

Our objective was to determine whether FDA followed the inspection and recall process for infant formula in accordance with Federal statutes and regulations and FDA policies and procedures. Specifically, we reviewed FDA's actions leading up to the infant formula recall at the Abbott facility in February 2022 to determine whether FDA followed applicable policies and procedures to: (1) conduct inspections of the manufacturing facility and (2) oversee Abbott's initiation of the infant formula recall.

BACKGROUND

FDA's Oversight of Infant Formula Manufacturing Facilities

The Federal Food, Drug, and Cosmetic Act (FD&C Act) grants FDA regulatory oversight to safeguard the Nation's food supply, including infant formula, and ensure that all ingredients are safe. FDA develops policies and procedures to hold infant formula manufacturers accountable to Federal requirements. FDA uses many resources to develop these policies and procedures, including statutes, regulations, and FDA guidance documents. We refer to these resources throughout this report. (See Appendix B for relevant criteria.) As part of its oversight activities, FDA receives, evaluates, and investigates complaints in accordance with its standard operating procedures (SOPs), and it conducts inspections at infant formula facilities in accordance with Federal regulations and internal FDA guidance, including its *Investigations Operations Manual* (IOM), *Regulatory Procedures Manual* (RPM), and infant formula compliance program guidance manual.[6] FDA also works with facilities to initiate recalls of infant formula products that present a risk to human health.

Within FDA, multiple offices collaborate to oversee the safety of infant formula, including the Office of Regulatory Affairs (ORA), the Center for Food Safety and Applied Nutrition (CFSAN), the Office of Food Policy and Response (OFPR), and the Office of Operations through the Office of Emergency Operations (OEO). FDA also coordinates with the Centers for Disease Control and Prevention (CDC) during illness and death investigations. See Appendix C for details on the responsibilities of the Department of Health and Human Services' (HHS's) offices involved in infant formula oversight. See Appendix D for ORA and CFSAN budget and staffing details.

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[5] *Challenges Remain in FDA's Inspections of Domestic Food Facilities* (OEI-02-14-00420) Sept. 25, 2017.

[6] In September 2023, the FDA updated its infant formula compliance program guidance manual to outline the agency's approach for inspections, sample collection, sample analysis, and compliance activities related to the oversight of infant formula. We did not assess implementation of the updated infant formula compliance program guidance manual as it was beyond the scope of our audit.

FDA Complaint Types

Three types of infant formula complaints can be reported to FDA: consumer complaints, whistleblower complaints, and adverse event reports. FDA generally follows up on open complaints during the next scheduled inspection.

Consumer complaints are notifications that a product in commercial distribution may be in violation of the laws and regulations FDA administers.[7] These complaints can come from consumers, other Government agencies, trade sources, or health care professionals through telephone calls, emails, or in-person meetings. ORA staff is responsible for receiving consumer complaints; recording consumer complaints in the Field Accomplishments & Compliance Tracking System (FACTS); and investigating consumer complaints based on the IOM, field management directives (FMDs), and SOPs. From January 2019 through June 2022 (audit period), FDA received and recorded at least 167 consumer complaints related to the Abbott facility.[8] Of the 167 complaints, 148 complaints were recorded on or after the date the Abbott recall was publicly announced (February 17, 2022); 19 were recorded from January 1, 2019, through February 16, 2022. Through reviews of the consumer complaints, FDA received and reported on its website four reports of hospitalizations, including two deaths of infants diagnosed with *Cronobacter* who had consumed powdered infant formula products produced at the Abbott facility. However, FDA could not confirm that the Abbott facility's products caused the infant illnesses or deaths because clinical isolates for the infants were not available or whole genome sequencing was not a match to the Abbott facility *Cronobacter* investigation findings (Appendix E).

Whistleblower complaints usually come from an employee or former employee who discloses information or activity within a private, public, or Government organization that is deemed illegal; illicit; unsafe; or a waste, fraud, or abuse of taxpayer funds.[9] In some cases, whistleblower reports are sent from the Occupational Safety and Health Administration (within the Department of Labor [DOL]) to the National Consumer Complaint Coordinator (NCCC) who works within OEO.[10] Whistleblower reports can also be received and recorded by ORA staff.

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[7] From FDA's consumer complaint policies and procedures (SOP-000544, version 00).

[8] There were an additional 40 infant formula consumer complaints that did not have an FDA Establishment Identifier (FEI) associated with the complaint. FDA assigns the FEI number to uniquely identify the facility associated with FDA regulated products. If a consumer complaint did not have an FEI number associated with it, we could not determine whether the consumer complaint was related to the Abbott facility.

[9] IOM (2022 version), chapter 8, § 8.1.5.7.2.4.

[10] DOL regulations specify that upon receipt of a complaint under the FDA Food Safety Modernization Act § 402 (21 U.S.C. § 399d), DOL will provide an unredacted copy of the complaint—including the filing of the complaint, the allegations contained in the complaint, and the substance of the evidence supporting the complaint—to the complainant (or the complainant's legal counsel if complainant is represented by counsel) and to FDA (29 CFR § 1987.104 (a)).

During our audit period, FDA recorded three whistleblower complaints related to the Abbott facility:[11]

- a February 2021 whistleblower complaint, originally sent to DOL, that DOL forwarded by email to FDA;

- an October 2021 whistleblower complaint sent by courier and email to FDA from the same whistleblower who submitted the February 2021 whistleblower complaint and with similar allegations to that complaint; and

- an April 2022 whistleblower complaint sent to FDA from a different individual that contained different information from the February and October 2021 whistleblower complaints.

Adverse event reports are notifications through FDA's MedWatch program and other reporting mechanisms that an infant formula may have contributed to a minor or major medical event or may have had other nonmedical issues, such as an off taste or off color or defective packaging.[12] According to FDA's Work Instruction for CFSAN Adverse Event Report System (CAERS) complaints, CFSAN is responsible for receiving and reviewing adverse event reports, determining whether the adverse events warrant further followup, and forwarding the adverse event reports to the NCCC. [13] The NCCC is then responsible for reviewing the adverse event reports and, if the adverse event reports warrant followup, forwarding the adverse event reports to the appropriate consumer complaint coordinator (within ORA) for investigation. During our audit period, FDA received 433 infant formula-related adverse event reports via CAERS.[14] Of the 433 infant formula-related adverse event reports, 283 adverse event reports were recorded on or after the date the Abbott recall was publicly announced (February 17, 2022); 150 were recorded from January 1, 2019, through February 16, 2022.

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[11] FDA also received a whistleblower complaint on June 29, 2022, related to possible violations of current good manufacturing practices at Abbott's Arizona facility.

[12] MedWatch is FDA's medical product safety reporting program for health professionals, patients, and consumers. MedWatch receives reports from the public and when appropriate publishes safety alerts for FDA-regulated products. MedWatch reports related to CFSAN-regulated products including infant formula are reported in the CAERS database. According to FDA, in addition to MedWatch reports, CAERS receives information for reports from the Safety Reporting Portal, FDA inboxes, and ORA systems such as the Field Accomplishment and Compliance Tracking system (FACTS), which collect consumer phone complaints.

[13] The CFSAN Adverse Event Reporting System (CAERS) website is available at https://www.fda.gov/food/compliance-enforcement-food/cfsan-adverse-event-reporting-system-caers. Accessed on May 20, 2024.

[14] Adverse event reports do not always identify a manufacturing facility; therefore, we could not determine how many of the 433 adverse event reports related to the Abbott facility.

FDA's Inspections of Infant Formula Manufacturing Facilities

FDA performs several types of inspections at infant formula manufacturers, including surveillance and for-cause inspections.[15] Surveillance inspections focus on systemwide controls to ensure that manufacturing processes produce infant formula in accordance with Federal regulations. For-cause inspections are triggered when FDA has reason to believe that a facility has serious manufacturing quality problems, when FDA wants to evaluate corrective actions that facilities have made to address previous violations, or to follow up on complaints.

Prior to June 2023, FDA's practice was to conduct annual surveillance inspections of infant formula manufacturers' facilities, though it was only required to inspect these facilities once every 3 years under the domestic high-risk food facility inspection requirements of the FDA Food Safety Modernization Act.[16, 17] Beginning in June 2023, FDA is required to inspect infant formula manufacturers not less than once per calendar year in accordance with a risk-based approach.[18] At the beginning of each fiscal year, CFSAN sends an infant formula inspection memo to ORA with the scheduled weeks for ORA to conduct surveillance inspections at infant formula manufacturing facilities during the year.

If FDA investigators observe significant objectionable conditions during surveillance or for-cause inspections, FDA issues an FDA Form 483 at the conclusion of the inspection, notifying the facility in writing of these observations. ORA writes an establishment inspection report (EIR) that details information about the facility, including its history, operations, complaints received, and FDA's observations. The ORA Division reviews this information and uses it to classify the FDA inspection.

FDA's Abbott Facility Inspections

Abbott manufactures infant formula products (under brands such as Similac, Alimentum, and EleCare) including specialty infant formulas for infants who have inborn errors of metabolism or low birth weight or who otherwise have medical or dietary problems. One of Abbott's six

[15] Previous Office of Inspector General (OIG) work focused on foreign for-cause drug inspections. *The Food and Drug Administration's Foreign For-Cause Drug Inspection Program Can Be Improved To Protect the Nation's Drug Supply* (A-01-19-01500) June 24, 2022.

[16] FDA, "How does the FDA oversee the safety and nutritional quality of infant formula?" Available online at https://www.fda.gov/food/resources-you-food/infant-formula#oversee. Accessed on May 20, 2024.

[17] FDA Food Safety Modernization Act § 201(a), amending and adding 21 U.S.C. 350j(a)(2)(B)(ii).

[18] Consolidation Appropriations Act, 2023 (P.L. 117-328) sec. 3401(i)(3).

domestic manufacturing facilities is in Sturgis, Michigan.[19] FDA investigators conducted infant formula inspections at the Abbott facility in 2019, 2021, and 2022, and FDA issued an FDA Form 483 to Abbott management each year detailing the inspectional observations.[20]

On May 16, 2022, Abbott entered into a consent decree settlement agreement with FDA and the Department of Justice.[21] The consent decree legally obligated Abbott to take specific actions to ensure that safe powdered infant formula is produced at the Abbott facility.[22] Since entry of the consent decree, FDA has conducted more frequent inspections at the Abbott facility. From June 2022 through December 2022, FDA conducted six inspections at the Abbott facility.[23] (See Appendix F for a description of activities that FDA conducted during the six inspections.) Prior to the consent decree, FDA generally conducted annual inspections at the Abbott facility.

FDA's Food and Infant Formula Recall Process

A recall is a manufacturer's removal or correction of a marketed product that FDA considers to be in violation of the laws it administers and against which FDA would initiate legal action, e.g., seizure.[24, 25] If a manufacturer has determined to voluntarily recall from the market infant formula that violates the laws and regulations FDA administers and would be subject to legal action, the manufacturer, upon prompt notification to FDA, must administer such voluntary recall consistent with the requirements under 21 CFR part 107, subpart E. If FDA determines

[19] According to FDA's 2022 EIR, the other five domestic manufacturing locations are: Columbus, Ohio; Tipp City, Ohio; Casa Grande, Arizona; Altavista, Virginia, and Fairfield, California. According to FDA, four of these sites manufacture infant formula.

[20] There was no inspection in 2020 because FDA suspended all routine inspections from Mar. 16, 2020, to June 30, 2021, due to the COVID-19 pandemic. The 2020 Abbott facility inspection was scheduled for the week of Sept. 21, 2020.

[21] A consent decree (also known as a consent order) is a decree made by a judge with the consent of all parties. It is not only a judgment but also a settlement agreement approved by the court. The agreement is submitted to the court in writing after the parties have reached a settlement, and once approved by the judge, the agreement is binding and enforceable on both parties. (See the Cornell Law School definition of "consent order." Available online at https://www.law.cornell.edu/wex/consent_order. Accessed on May 20, 2024.

[22] *U.S., v. Abbott Laboratories,* Case No. 1:22-cv-441, W.D. Mich. (2022). Available online at https://dam.abbott.com/en-us/documents/pdfs/transparency/ECF-008-Consent-Decree.pdf. Accessed on May 20, 2024.

[23] FDA's Inspection Dashboard. Available online at https://datadashboard.fda.gov/ora/firmprofile.htm?FEIi=1815692&/identity/1815692. Accessed on May 20, 2024.

[24] Food recalls are usually voluntarily initiated by the manufacturer or distributor of the food. In some situations, the FDA may request or mandate a recall.

[25] 21 CFR § 7.3.

that an adulterated or misbranded infant formula presents a risk to human health, FDA can require a manufacturer to immediately take all actions necessary to recall that formula.[26] (We refer to this as an "FDA-required recall.")

On January 31, 2022, FDA began conducting a for-cause inspection of the Abbott facility, and on February 7, 2022, FDA learned that samples collected during the ongoing Abbott facility inspection returned an initial "Cannot Rule Out" (CRO) result for *Cronobacter*. On February 14 and 15, 2022, the CRO results were confirmed positive for *Cronobacter* in nonproduct contact areas of the facility. Through whole genome sequencing, FDA was not able to match these positive *Cronobacter* samples to samples collected from sick infants.

On February 17, 2022, after being presented with FDA sample results, Abbott initiated a voluntary recall of powdered infant formulas, including Similac, Alimentum, and EleCare, manufactured at the Abbott facility. On February 28, 2022, Abbott voluntarily expanded its recall to one lot of Similac PM 60/40 that was manufactured at the Abbott facility after FDA received an additional complaint related to *Cronobacter* in an infant who consumed Similac PM 60/40. (See Appendix G for a complete timeline of events. See Appendix H for events after the recall.)

HOW WE CONDUCTED THIS AUDIT

For the audit period (January 1, 2019, through June 30, 2022), we reviewed FDA's ability to identify, escalate, and appropriately manage the February 2021 and October 2021 whistleblower complaints related to the Abbott facility.[27] We also reviewed 48 infant formula consumer complaints involving life-threatening illness or death among infants who consumed infant formula manufactured at the Abbott facility, 15 randomly selected infant formula consumer complaints that were not life threatening or had no adverse event related to the Abbott facility, and 15 randomly selected infant formula adverse event reports. For the consumer complaints and adverse events, we determined:

- whether CFSAN forwarded the adverse event report to OEO and the time it took to forward the adverse event to OEO (for adverse event reports);

- whether OEO forwarded the adverse event report to ORA and the time it took to forward the adverse event to ORA (for adverse event reports);

- whether ORA notified OEO of the complaint and the time it took to notify OEO (for consumer complaints);

[26] 21 CFR § 107.200.

[27] The third whistleblower complaint, which FDA received in April 2022, was identified and reviewed through the 15 randomly selected infant formula consumer complaints that were not life threatening or had no adverse event.

- the time it took FDA to determine the initial disposition; and

- the time it took FDA to complete the followup actions, including inspections, investigations, and sample collection.

We also interviewed FDA personnel responsible for scheduling inspections, conducting inspections, and assisting manufacturers in initiating recalls. In addition, we reviewed the EIRs for the September 2019, September 2021, and January 2022 Abbott facility inspections, as well as other relevant information. We also obtained and reviewed information related to the initiation of the February 17, 2022, and the February 28, 2022, Abbott recalls.

Further, we reviewed Federal laws and regulations; FDA's internal written policies and procedures; and industry guidance FDA published regarding complaints, whistleblowers, infant formula, recalls, and inspections of infant formula facilities. We also reviewed standards in the Government Accountability Office's (GAO's) *Standards for Internal Control in the Federal Government* that we determined were relevant to our audit objective.[28]

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A contains the details of our audit scope and methodology.

FINDINGS

Although FDA followed applicable inspection and recall processes for infant formula in accordance with Federal requirements, improvements in its inspection and recall processes are needed to better ensure the safety of the infant formula supply. We found that FDA: (1) 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; and (2) did not have the authority to require individuals and manufacturers to provide information that may have helped FDA to identify and respond to risks to the infant formula supply. If FDA had adequate policies and procedures and authority to obtain information, it could have identified underlying problems at the Abbott facility and required Abbott to correct them.

[28] GAO, *Standards for Internal Control in the Federal Government*, September 2014. Available online at https://www.gao.gov/assets/gao-14-704g.pdf. Accessed on May 20, 2024.

FDA DID NOT HAVE ADEQUATE POLICIES AND PROCEDURES OR LACKED POLICIES AND PROCEDURES

FDA did not have adequate policies and procedures or lacked policies and procedures to identify risks to infant formula and respond to the risks effectively through its complaints, inspections, and recall processes.

FDA Did Not Have Adequate Policies and Procedures To Identify the February 2021 Whistleblower Complaint

FDA did not have adequate policies and procedures to identify and investigate the February 2021 Abbott facility whistleblower complaint. Specifically, the whistleblower's attorney originally sent the whistleblower complaint to the DOL on February 16, 2021. The whistleblower complaint alleged that the Abbott facility engaged in practices that violated laws, regulations, and other guidance that FDA administered and enforced. DOL forwarded the whistleblower complaint to the dedicated FDA whistleblower email inbox on February 19, 2021. FDA, however, did not identify the whistleblower complaint or forward it to ORA until June 7, 2022, more than 15 months after the complaint was sent to FDA. (See Figure 1.)

Figure 1: It Took FDA More Than 15 Months To Identify and Forward a Whistleblower Complaint

At the time of the initial submission of the February 2021 whistleblower complaint, FDA did not have adequate policies and procedures for identifying and investigating whistleblower complaints received in the dedicated FDA email inbox. FDA implemented new whistleblower complaint procedures on June 9, 2022. The new procedures assigned to certain FDA officials the responsibility for monitoring the dedicated FDA email inbox for whistleblower complaints and for assigning whistleblower reports (as appropriate) to ORA district offices. The procedures state that FDA will regularly coordinate with DOL to discuss points of contact for whistleblower complaints, information sharing, investigative assistance, ongoing cases, outreach and training, and current events. Although we did not audit the effectiveness of the complaint procedures that FDA adopted in June 2022, if effectively implemented they should assist in identifying and accounting for whistleblower complaints.

We also found that, with regard to whistleblower complaints, FDA did not develop an organizational structure or assign responsibilities to enable the organization to operate in an efficient and effective manner. According to FDA officials, in February 2021, FDA did not have a permanent NCCC, and the NCCC position was covered by other individuals. When there is not a permanent NCCC, FDA assigns the NCCC's duties to other individuals to maintain the continuity of operations. The NCCC plays an important role in: (1) identifying and accounting for whistleblower complaints by monitoring email inboxes for whistleblower complaints, (2) assigning whistleblower complaints to the appropriate district office or center, and (3) recording receipt and followup activities for all whistleblower complaints. FDA provided documentation showing that the NCCC position was vacant from January 5, 2020, through July 31, 2021, and was filled on August 1, 2021. The individuals covering the NCCC's duties in February 2021 had other responsibilities and did not identify the February 2021 whistleblower complaint when DOL sent it. FDA stated that an individual covering the NCCC's responsibilities inadvertently archived the February 2021 whistleblower complaint and did not forward it to ORA for investigation. FDA identified the February 2021 whistleblower complaint and forwarded the complaint to ORA in June 2022 following a search prompted by a press inquiry about the whistleblower complaint.

FDA Did Not Have Adequate Policies and Procedures To Escalate the October 2021 Whistleblower Complaint

In addition to FDA not having adequate policies and procedures for identifying and forwarding whistleblower complaints to ORA, FDA did not have adequate policies and procedures to escalate the October 2021 whistleblower complaint to senior leadership.[29] Specifically, in October 2021, the whistleblower's attorney sent hardcopy whistleblower complaints via a courier to seven FDA employees. These seven senior officials included the Acting FDA Commissioner, the CFSAN Director, the Associate Commissioner of Regulatory Affairs, the FDA Medical Director for Infant Formula and Medical Foods, and certain ORA district directors.[30] In addition to the courier mailing, the whistleblower's attorney emailed a copy of the complaint to certain ORA district directors, ORA district staff, and the FDA Medical Director for Infant Formula and Medical Foods. The ORA district staff that received the October 2021 whistleblower complaint via email acknowledged receipt of the email on October 21, 2021.

[29] Prior to July 26, 2021, FDA did not have written procedures related to the process for receiving, recording, investigating, and escalating whistleblower complaints to senior leadership. FDA would handle whistleblower complaints in the same manner as consumer complaints, according to FDA officials, meaning that whistleblower complaints would be received, entered into the complaint system, investigated, and followed up on in accordance with consumer complaint policies and procedures. On July 26, 2021, FDA formalized its prior unwritten policy by adding language to the IOM stating that whistleblower complaints would be treated in the same manner as consumer complaints.

[30] FDA senior leadership did not receive the October 2021 whistleblower complaint because, according to FDA, there were likely mailroom staffing issues due to COVID-19 that prevented the hardcopies from reaching FDA senior leaders.

According to FDA officials, FDA senior leadership (including the Acting FDA Commissioner, the Associate Commissioner for Regulatory Affairs, and the CFSAN Director) did not receive the October 2021 whistleblower complaint until February 14, 2022, nearly 4 months after the whistleblower complaint was submitted. Further, the FDA Deputy Commissioner for Food Policy and Response was not notified of the whistleblower complaint until February 10, 2022. During a March 2023 congressional hearing, the former FDA Deputy Commissioner for Food Policy and Response stated, "Some individuals received copies [of the October whistleblower complaint] by emails and in hindsight, those should have been escalated to my office very rapidly."[31]

The whistleblower complaint sent electronically to FDA was not escalated to senior leadership due to a lack of complaint escalation policies and procedures, and according to FDA, whistleblower complaints sent via courier were not delivered to FDA senior leadership due to issues in the FDA mailroom. After our audit period, FDA implemented new whistleblower complaint procedures, including complaint escalation procedures that assign certain FDA officials the responsibility for escalating issues, including whistleblower complaints, to senior leadership as necessary. Although we did not audit the effectiveness of the complaint procedures that FDA adopted in July 2022, if effectively implemented, FDA's new procedures should result in whistleblower complaints being communicated to senior leadership quicker. Without whistleblower complaint escalation policies and procedures, FDA senior leadership was unable to make informed decisions to minimize risks related to the Abbott facility and the infant formula supply chain.

FDA Did Not Have Adequate Policies and Procedures To Communicate Consumer Complaints to Investigators

FDA did not have adequate policies and procedures to communicate relevant consumer complaint information to its investigators. Specifically, FDA began an inspection at the Abbott facility on September 20, 2021. According to FDA, the investigator reviewed the Abbott facility consumer complaint history prior to the start of the inspection. Also, on September 20, 2021 (after the investigator reviewed the Abbott facility consumer complaint history), FDA received and entered into its complaint system a new consumer complaint related to an infant who was diagnosed with a *Cronobacter* infection after consuming infant formula manufactured at the Abbott facility. According to FDA, its personnel reviewing the new consumer complaint were not aware of the inspection taking place at the Abbott facility and did not communicate the complaint to the investigator during the week of September 20, 2021. As a result, the investigation team conducting the inspection at the Abbott facility was not informed of the new consumer complaint until after the inspection closed.

[31] House Committee on Oversight and Accountability, *FDA Oversight Part I: The Infant Formula Shortage* (beginning at 1:09:40), Mar. 28, 2023. Available online at https://oversight.house.gov/hearing/fda-oversight-part-i-the-infant-formula-shortage. Accessed on May 20, 2024.

We also noted that FDA's electronic system is designed for recording and tracking complaints. However, the electronic system was not designed to alert an investigator if a new consumer complaint is entered into the system while the investigator is at the facility conducting an inspection. Without determining whether there was an active inspection and informing the investigators of any new complaints since the start of the inspection, FDA was not using all relevant information to address risks at the facility. As a result, the FDA investigator could not review and consider information from the new consumer complaint to better inform the ongoing inspection at the Abbott facility.

FDA Did Not Have Adequate Policies and Procedures To Identify and Correct Infant Formula Consumer Complaint Data Inaccuracies

FDA did not have adequate quality control procedures to identify and correct infant formula consumer complaint data that it entered inaccurately in its system. FDA did not accurately record all infant formula consumer complaint data for 37 of 63 complaints we reviewed. Based on our analysis and responses from FDA officials related to the 37 consumer complaints, we identified the following data inaccuracies:

- For 32 consumer complaints, FDA did not enter information on planned followup assignments.[32, 33]

- For six consumer complaints, the consumer complaint information FDA entered contained an inaccurate complaint result (i.e., death, life-threatening injury/illness, non-life-threatening injury/illness, and none).

- For five consumer complaints, the consumer complaint initial disposition was not updated by FDA in a timely manner to reflect FDA's intent.[34]

- For two consumer complaints, the consumer complaint information FDA entered had incorrect data in the illness onset date field. In one instance, FDA updated the date

[32] Followup assignments could include an investigation, sample collection, or a review of the complaint during the next inspection.

[33] For 32 of the 48 infant formula consumer complaints involving life-threatening illness or death among infants who consumed infant formula manufactured at the Abbott facility, we compared data FDA originally provided in July 2022 to updated complaint data FDA provided in January 2023 to determine if FDA changed the consumer complaint data between July 2022 and January 2023. Further, for 5 of the 15 randomly selected infant formula consumer complaints that were not life threatening or had no adverse event related to the Abbott facility, we questioned FDA about information in the consumer complaint.

[34] The initial disposition shows FDA's responsibility or intent regarding the complaint, which may include immediate followup or surveillance next inspection. For 61 of the 63 complaints, the average time for FDA to assign the initial disposition was 43 days (30 business days). For the remaining 2 complaints, FDA did not have an initial disposition date listed in the complaint information.

from February 25, 2022, to January 25, 2022. In the other instance, FDA updated the date from January 20, 2021, to January 20, 2022.

FDA uses quality factor checklists (QFCs) to assist in identifying issues with consumer complaints; however, the QFCs are not designed to capture the data inaccuracies that we identified.[35]

Inadequate QFC procedures could result in incorrect data in FACTS leading to inaccurate information reported to management and the public. If incorrect information is recorded in FACTS and used by management to make decisions, management could make uninformed decisions related to consumer complaint followup actions. Inaccurate information can also become public through the Freedom of Information Act and media coverage. For example, according to an article in *The Washington Post*, from December 2021 to March 2022, "as many as nine children have died since early 2021 after consuming baby formula produced at an Abbott Nutrition plant in Michigan—seven more than previously acknowledged by the FDA, according to newly released documents."[36] *The Washington Post's* count of nine children who died since 2021 included a consumer complaint that FDA had first recorded as "death" but later changed to "life threatening injury/illness" to correct the classification after the published article.[37] Further, FDA officials told us that FDA made changes after its internal review identified errors found in complaint data entered into FACTS. The officials said FDA updated the data to correctly reflect the complaint information.

[35] FDA randomly selects consumer complaints for review based on a sample plan documented in its QFC procedures (SOP-000108).

[36] Laura Reiley, "New documents show more claims of baby formula illness and death," *The Washington Post*, June 10, 2022. Available online at https://www.washingtonpost.com/business/2022/06/10/baby-formula-deaths-abbott. Accessed on May 20, 2024.

[37] From Dec. 1, 2021, to Mar. 2, 2022 (the period that relates to *The Washington Post* article), FDA recorded nine Abbott facility consumer complaints involving an infant death. From Mar. 3, 2022, to June 30, 2022, FDA recorded eight additional Abbott facility consumer complaints involving an infant death. In total, FDA recorded 17 Abbott facility consumer complaints involving an infant death; however, we identified 1 consumer complaint that was classified as a death when it should have been classified as a life-threatening injury/illness. We also note that although all complaints relate to infant formula products manufactured at the Abbott facility, FDA has not directly linked any illnesses or deaths to consuming infant formula produced at the Abbott facility.

FDA's Policies and Procedures Did Not Identify Specific Factors To Determine Which Adverse Event Complaints Should Be Communicated to the NCCC

FDA's policies and procedures did not identify specific factors to determine which adverse event complaints should be communicated to the NCCC.[38] Specifically, for 3 of the 12 adverse event reports we reviewed that originated in CAERS, the adverse events reports were not forwarded to the NCCC:[39]

- For two of the adverse event reports, FDA stated that resources were not available within CFSAN and OEO to coordinate and reconcile CAERS and FACTS reports.

- For one of the adverse event reports, FDA stated that the report did not concern a serious adverse event and that there was no way for FDA to follow up given that the report contained no product lot number or contact information. Based on our review of the adverse event report, the reporter checked a box stating that the infant was hurt or had a bad side effect and reported that the infant "began to vomit an entire bottle" of formula. We also noted that the reporter provided their name and email address. Therefore, FDA could have followed up on this adverse event by contacting the complainant to get more information about the adverse event report. According to FDA, it made an error in stating that there was no contact information associated with the adverse event report.

FDA's policies and procedures did not identify specific factors to determine which adverse event complaints should be communicated to the NCCC. In May 2021, FDA implemented informal, unwritten policies and procedures. Specifically, to improve information-sharing processes between CFSAN and OEO, the CAERS coordinator put into practice that all complaints in CAERS that did not originate in FACTS would be forwarded to the NCCC.[40] FDA should formalize the procedures, and if effectively implemented, FDA's new procedures should result in all adverse event reports being forwarded to the NCCC. Without clear policies and procedures to determine which adverse event complaints should be communicated to the

[38] FDA's policies and procedures state that members of CFSAN (the CAERS team) review each complaint, and if they determine that it warrants further follow up, they forward the complaint to OEO (the NCCC). According to FDA, the CAERS team determines whether followup is necessary on a case-by-case basis, collaborating with multiple program offices and subject matter experts. CAERS complaints must contain certain information such as identifiable product or reporter contact information to perform followup steps. The NCCC's role is to serve as a liaison between CFSAN and ORA. The NCCC is also responsible for using data to perform trend analysis to assist in identifying potential health and safety concerns.

[39] We reviewed a total of 15 adverse event reports. Twelve adverse event reports originated in CAERS. The remaining three adverse event reports originated in FACTS and then were uploaded to the CAERS database for the purposes of trend analysis. The NCCC was made aware of these reports through the consumer complaint process.

[40] Adverse event reports can originate in FACTS and then get uploaded into CAERS, or they can originate from other sources before entry into CAERS.

NCCC, the NCCC cannot use adverse event data to assist in identifying trends that aid in identifying potential health and safety issues.

FDA Did Not Have Policies and Procedures To Establish Timeframes for the Initiation of Mission-Critical Inspections

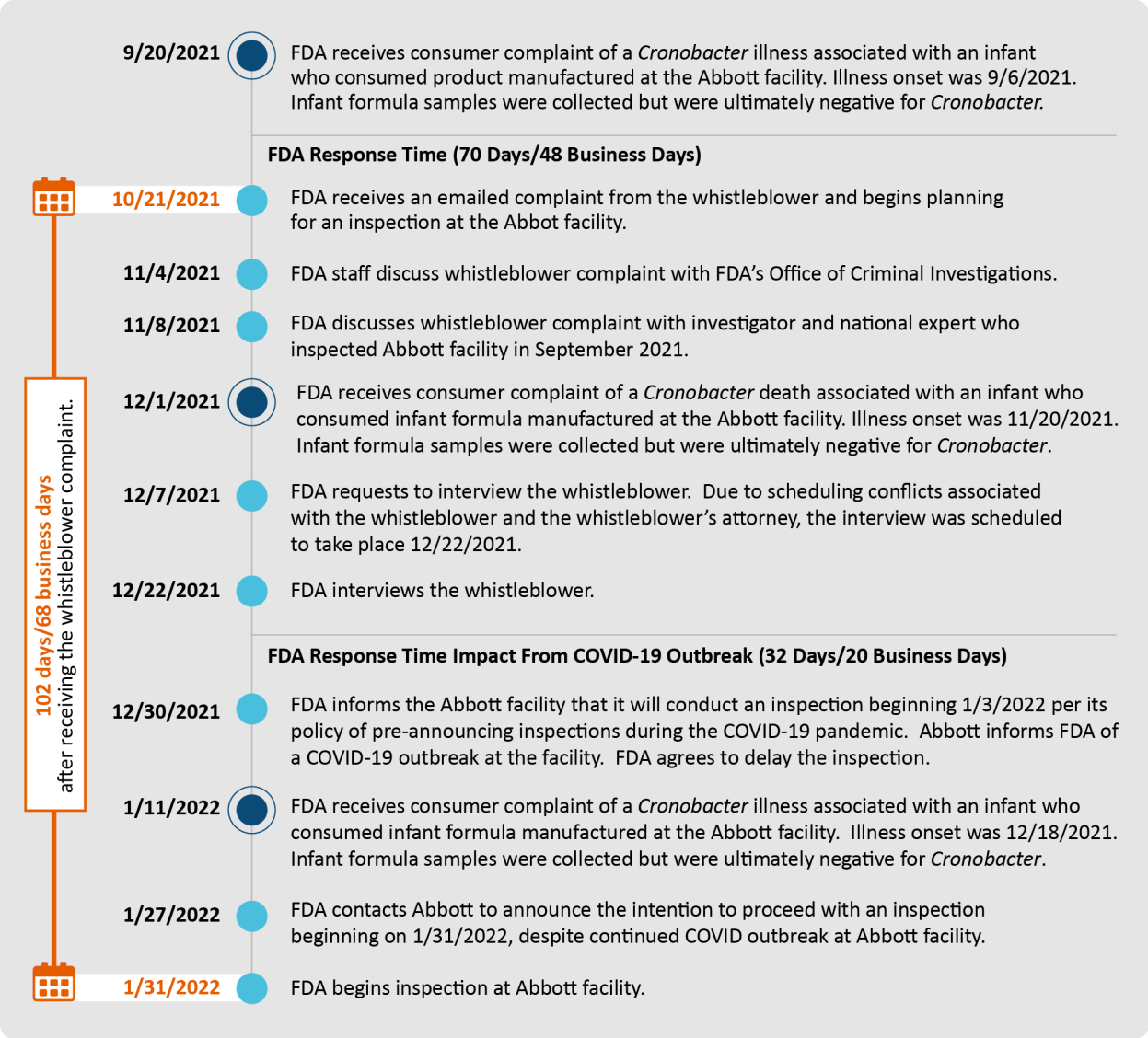
FDA did not have policies and procedures to establish timeframes for the initiation of mission-critical inspections. In March 2020, FDA suspended most foreign and domestic inspections because of the COVID-19 pandemic except for "mission-critical inspectional work." In May 2021, FDA issued a report titled *Resiliency Roadmap for FDA Inspectional Oversight* that detailed the effects of the pandemic on its inspection activities for each regulated commodity in FDA's portfolio and a plan for a more consistent state of operations and priorities going forward.[41] The report also established several factors FDA should consider when determining the need for mission-critical inspections, including whether there is evidence of serious adverse events or outbreaks of a foodborne illness. Although the report establishes several factors for determining mission-critical inspections, it does not establish how and when to initiate mission-critical inspections during public health emergencies.

According to FDA officials, the January 31, 2022, inspection at the Abbott facility was a for-cause inspection that met the definition of "mission critical." FDA received a consumer complaint on September 20, 2021, associated with an infant that consumed product manufactured at the Abbott facility. About 1 month later, FDA received a whistleblower complaint on October 21, 2021, and initially contacted Abbott to preannounce the inspection on December 30, 2021.[42] On December 30, 2021, Abbott informed FDA of a COVID-19 outbreak at the Abbott facility. FDA management decided to postpone the inspection because of the COVID-19 outbreak. This mission-critical, for-cause inspection was not initiated until January 31, 2022, which was 102 days (68 business days) after receiving the October 2021 whistleblower complaint. (See Figure 2 on the next page.)

[41] FDA, *Resiliency Roadmap for FDA Inspectional Oversight.* Available online at https://www.fda.gov/media/148197/download. Accessed on May 20, 2024.

[42] Although scheduling conflicts associated with the whistleblower and whistleblower's attorney prevented FDA from interviewing the whistleblower between Dec. 7, 2021, and Dec. 22, 2021, there is nothing that prevented FDA from initiating the mission-critical inspection prior to interviewing the whistleblower.

Figure 2: Timeline To Initiate For-Cause Abbott Facility Inspection



Although FDA's report did not establish timeframes for FDA to initiate mission-critical inspections, FDA acknowledged that it could have acted sooner to initiate the mission-critical inspection. In retrospect and comparing insights gained during the 2021 inspection, FDA officials said that the agency could have acted sooner to conduct the 2022 inspection. Further, during a May 2022 congressional hearing, the FDA Commissioner stated, "FDA's timeliness of interviewing the whistleblower and getting into the facility for a for-cause inspection were too slow, and some decisions in retrospect could have been more optimal."[43] Had FDA initiated the

[43] United States House of Representatives, Subcommittee on Oversight and Investigations, "Formula Safety and Supply: Protecting The Health of America's Babies" (lines 690 to 693), May 25, 2022. Available online at https://www.congress.gov/117/meeting/house/114821/documents/HHRG-117-IF02-Transcript-20220525.pdf. Accessed on May 20, 2024.

Abbott facility inspection sooner, FDA may have identified the issues at the Abbott facility and recommended that Abbott recall products sooner.

FDA Did Not Have Adequate Policies and Procedures for Initiating an FDA-Required Recall

FDA did not have sufficient policies and procedures that provided detailed guidance on how to initiate an infant formula recall under its FDA-required recall authority.[44] In addition, FDA told us that the FDA-required infant formula recall authority has not been used by the agency in the last several years. FDA stated that if it elected to initiate an FDA-required infant formula recall, it would use the same procedures as it would use to initiate a recall using its mandatory food recall authority (under section 423 of the FD&C Act). However, the FDA-required recall authority requirements are more stringent on infant formula manufacturers than mandatory food recalls authorized by section 423.[45]

Under the FDA-required recall authority for infant formula, manufacturers must "immediately" take all actions necessary to recall the infant formula if FDA determines it presents a risk to human health. Without additional specific policies, procedures, or guidance that implement its FDA-required recall authority for infant formula, FDA is not well positioned to immediately initiate an infant formula recall when infant formula presents a health risk.[46]

FDA DID NOT HAVE THE AUTHORITY TO REQUIRE INDIVIDUALS AND MANUFACTURERS TO PROVIDE INFORMATION THAT MAY HAVE HELPED FDA IDENTIFY AND RESPOND TO RISKS IN THE INFANT FORMULA SUPPLY

FDA's ability to respond to risks to the infant formula supply was limited. Adverse event reports submitted to FDA did not consistently include product lot numbers, and this limited FDA's ability to identify the facility that manufactured the infant formula. In addition, manufacturers are not required to notify FDA of positive pathogen test results for infant formula that has not been distributed.

[44] According to 21 CFR § 107.200, when FDA determines that an adulterated or misbranded infant formula presents a risk to human health, a manufacturer must immediately take all actions necessary to recall that formula, extending to and including the retail level.

[45] FDA, "Questions and Answers Regarding Mandatory Food Recalls: Guidance for Industry and FDA Staff," November 2018. Available online at https://www.fda.gov/media/117429/download. Accessed on May 20, 2024.

[46] According to FDA's Annual Report on the Use of Mandatory Recall Authority submitted to Congress, as of the end of FY 2022, the last time FDA issued a mandatory recall order for a food product was in FY 2018 when FDA determined that there was a reasonable probability that all food products containing powdered kratom manufactured, processed, packed, or held by Triangle Pharmanaturals, LLC, were adulterated after in-process and finished products tested positive for *Salmonella*.

Adverse Event Reports Did Not Consistently Include Product Lot Numbers

The CAERS database contains information on adverse event and product complaint reports submitted to FDA for foods including infant formula, according to FDA's website. CAERS is a useful tool for FDA activities, such as looking for new safety concerns that might be related to a marketed product. If a potential safety concern is identified in CAERS, further evaluation is performed. Based on an evaluation of the potential safety concern, FDA may take regulatory actions to improve product safety and protect the public health; communicate new safety information to the public; or, in rare cases, remove a product from the market.

When submitting an adverse event report in MedWatch, the reporter cannot submit the electronic adverse event report without providing the following information: (1) responses to questions about how and what the problem is; (2) whether there was a problem with a product or medical device; (3) the name of the product as it appears on the box, bottle, or package; and (4) the reporter's first and last name or "anonymous" listed as the first and last name.

Although FDA collected adverse event data in the CAERS database, individuals submitting adverse event reports to FDA did not consistently include product lot numbers, which limited FDA's ability to identify the facility that manufactured the infant formula.[47] Specifically, for adverse event reports, FDA has an optional data field for "product lot number."[48] If adverse event reporters do not submit lot information, FDA cannot use CAERS data to identify safety concerns at a specific manufacturer or site for products that are manufactured at multiple sites. For example, the 2022 EIR states that Abbott has five other domestic manufacturing locations. If an adverse event is reported in CAERS related to a Similac product but the product lot number is not submitted, FDA would not know which facility manufactured the product and would not be able to quickly identify a potential safety concern at a specific facility based solely on the required information in CAERS. FDA relies on the public to voluntarily report information. There may be opportunities for FDA to better encourage the public to report lot number information that may be useful for addressing safety concerns.

[47] We reviewed 433 infant formula-related adverse event reports. Of the 433 adverse event reports, 225 did not contain product lot numbers.

[48] In general, FDA regulations define a lot number as any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of drug, product, or other material can be determined. According to the 2022 EIR, the Abbott facility uses a nine-digit code system in which the first two digits represent the month and year the product was manufactured, the third through fifth digits represent a numeric sequence number, the sixth and seventh digits represent the manufacturing location, and the eighth and ninth digits identify any sub-batches.

Manufacturers Are Not Required To Notify FDA of Positive Pathogen Test Results for Undistributed Infant Formula

Under the FD&C Act, infant formula manufacturers are not required to report positive *Cronobacter* results or provide the bacterial isolate to FDA for infant formula that has not been distributed.[49] In March 2023, FDA requested in written formal communications that facilities voluntarily notify FDA if product samples were positive for *Cronobacter* or *Salmonella*, even if the affected lots had not been distributed.[50] The Abbott facility had three positive tests of *Cronobacter* in finished products that had not been distributed during our audit period. In all three cases, FDA was unaware of the positive *Cronobacter* results until FDA arrived at the Abbott facility to conduct an inspection and investigators noted that the Abbott facility had nonconformance reports (NCRs) with positive *Cronobacter* test results.[51] In two of these cases, the Abbott facility created *Cronobacter*-positive finished product NCRs in September 2019 and June 2020, and FDA was unaware of these NCRs for more than a year until September 2021 when FDA conducted the 2021 inspection. If FDA does not receive a timely notification every time a manufacturer finds a product sample that is positive for *Cronobacter* or *Salmonella*, even if the affected lots have not been distributed, FDA cannot adequately assess the risk at a specific manufacturing site.

FDA was unaware of the positive *Cronobacter* results at the Abbott facility because the FD&C Act did not require Abbott to report the positive *Cronobacter* test results to FDA unless the infant formula product was distributed by the manufacturer. FDA requested in its fiscal year (FY) 2024 legislative proposal that Congress authorize FDA to require infant formula manufacturers to notify FDA every time a product sample is positive for *Cronobacter* or *Salmonella*, even if the affected product has not been distributed. After our audit period, a bill was introduced that would require infant formula manufacturers to notify FDA—and provide FDA with positive infant formula samples—if a manufacturer has knowledge that reasonably supports the conclusion that an infant formula may be adulterated due to pathogen contamination, regardless of whether the infant formula has left the control of the

[49] According to CDC's website, culture-independent diagnostic tests are changing the way that clinical laboratories diagnose patients with foodborne illness. These tests can identify the general type of bacteria-causing illness within hours, without having to culture or grow the bacteria in a laboratory. The pure bacterial strain that grows is called an isolate.

[50] In March 2023, FDA issued a letter directed to manufacturers, packers, distributors, exporters, importers, and retailers involved in the manufacturing and distribution of powdered infant formula. In the letter FDA asked that manufacturers voluntarily notify FDA any time a product sample is found to be positive for *Cronobacter* or *Salmonella*, even if the affected lots have not been distributed.

[51] An NCR is typically generated when a product does not meet specifications or when there is an issue with the manufacturing process. NCRs contain the Abbott facility's nonconformance description, nonconformance impact assessment, risk evaluation, medical/safety review, regulatory review, and planned correction.

manufacturer.[52] If a manufacturer notifies FDA of positive *Cronobacter* test results even if products have not been distributed, FDA can better assess the risks at that facility.

CONCLUSION

FDA's policies and procedures were inadequate to identify risks to the infant formula supply chain. Specifically, FDA's inadequate policies and procedures or lack of policies and procedures contributed to: (1) delays in its response to the February and October 2021 whistleblower complaints, (2) investigators not receiving information from a relevant consumer complaint while they were conducting an inspection, and (3) investigators not knowing how and when to initiate the 2022 for-cause inspection during the public health emergency. FDA should improve its inspection and recall processes to better ensure the safety of the infant formula supply.

If FDA had adequate policies and procedures, it could have identified underlying problems at the Abbott facility and required Abbott to correct them. Although FDA took some action during the facility inspections and conducted followup inspections in accordance with Federal regulations and internal policies and procedures (Appendix I), our audit results demonstrate that more could have been done leading up to the Abbott powdered infant formula recall.

RECOMMENDATIONS

We recommend that the Food and Drug Administration:

- prioritize maintaining the NCCC's continuity of operations by cross-training staff on whistleblower policies and procedures and NCCC duties, including monitoring the Occupational Safety and Health Administration whistleblower email inbox;

- develop and implement policies and procedures requiring periodic reporting (e.g., monthly reporting) to senior leadership on the status of open whistleblower complaints;

- implement policies and procedures that facilitate reporting consumer complaints in real time to investigators onsite when an active inspection is occurring at the facility identified in the complaint;

- strengthen the QFC process to identify data entry inaccuracies;

- formalize written policies and procedures that either:

[52] H.R. 5316: Safeguarding Kids and Families from Critical Food Disruptions Act of 2023 (Aug. 29, 2023). Available online at https://www.congress.gov/bill/118th-congress/house-bill/5316/text?s=1&r=2&q=%7B%22search%22%3A%22hr+5316%22%7D. Accessed on May 20, 2024.

- require that the CAERS coordinator forward all reports that originate in CAERS to the NCCC or

- identify specific factors that the CAERS coordinator must consider when determining if adverse event reports should be forwarded to the NCCC, and include specific examples of types of adverse event reports that do not need to be forwarded to the NCCC;

- 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 mission-critical inspections are conducted in a timely manner;

- design and implement policies and procedures specific to the use of its FDA-required infant formula recall authority;

- amend the language on the CAERS adverse event report form to emphasize the importance of including the lot number to encourage the public to report this information; and

- continue to seek legislative authority to require infant formula manufacturers to notify and provide the bacterial isolate to FDA every time a product sample is found to be positive for *Cronobacter* or *Salmonella*, even if the affected lots have not been distributed, and update its existing databases with the information received.

FDA COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

FDA COMMENTS

In written comments on our draft report, FDA concurred with our recommendations and findings that FDA: (1) 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; and (2) did not have the authority to require individuals and manufacturers to provide information that may have helped FDA to identify and respond to risks to the infant formula supply. FDA stated that it strongly agrees that adequate policies, procedures, and authorities are needed, and that delays due to poor procedures are unacceptable and must be corrected. FDA indicated its commitment to implementing the Office of Inspector General's (OIG's) recommendations for strengthening its program and has begun several steps to improve policies and procedures for complaints, recalls, and infant formula inspections. FDA also stated that it will continue to pursue additional authority as OIG recommends. Examples of actions FDA described it has taken and plans to take to address our recommendations include the following:

- For whistleblower complaints, FDA stated that its CFSAN's Office of Compliance has developed a process to track, evaluate, follow up, and notify compliance leadership of regulatory misconduct complaints, which includes whistleblower complaints.

- For all infant formula-related events, including whistleblower complaints, FDA stated that CFSAN has developed a leadership notification memorandum, which lays out which infant formula-related events will be elevated to the highest levels of FDA leadership, who in FDA leadership will receive the notifications, which office will be responsible for sending the notifications, and generally what information will be contained within a notification.

- For consumer complaints, FDA stated that it is working on longer term IT improvements that will make its currently manual process a systematic one for compiling and sharing compliant data across FDA to help inspection preparation. In addition, FDA's ORA and CFSAN components have created elevation distribution lists, SOPs, and mechanisms for emerging public health issues to be shared across FDA centers.

- For continuing to seek legislative authority, FDA indicated that in its FY 2024 budget request it formally requested the authority to require infant formula manufacturers to notify FDA of any product that tests positive for pathogen contamination, regardless of the disposition of that product.

In addition, FDA noted in its comments that the report contains some statements that do not align with the available evidence. Specifically, FDA stated that the report presents findings and conclusions that at least four reported illnesses, including two deaths, may have been preventable. FDA states that these statements are predicated on a possible causal link between the Abbott facility and the reported cases, which was not substantiated by evidence from the investigation. Lacking evidence of causation, FDA is not aware of other sufficient or appropriate evidence to support postulation. At a minimum, FDA believes that these findings and conclusions about illness prevention are incomplete and potentially misleading unless revised to clarify that evidence from the investigation does not substantiate a causal link between the Abbott facility and the reported cases.

FDA also provided written technical comments, which we addressed as appropriate. FDA comments, excluding the technical comments, are included as Appendix J.

OFFICE OF INSPECTOR GENERAL RESPONSE

We appreciate FDA's cooperation during the course of our audit and the proactive steps it has taken thus far to address our report findings and recommendations. In considering FDA's comments, we removed our statement that a more timely FDA response may have prevented at least four infant illnesses, including two infant deaths. We previously included this statement in the report because we obtained a signed (March 28, 2022) health hazard

evaluation (HHE) related to infant formula manufactured at the Abbott facility.[53] In the HHE, FDA concluded that the present case series demonstrated that the probability of infection with *Cronobacter* was likely to occur and that "receipt of four consumer complaints describing [*Cronobacter]* infection during a six-month period involving infants who ingested, prior to onset of illness, powdered infant formula products manufactured at a single facility (Abbott Nutrition, Sturgis, MI) supports a conclusion that this was a case series linked to a common production facility." We acknowledge the laboratory analysis did not find a genetic match to the strains of *Cronobacter* found in the Abbott facility, and the bacteria from these patient samples were not closely related to one another. However, timely and effective identification and response to risks is essential to protecting public health.

OTHER MATTERS

BETTER DOCUMENTATION NEEDED FOR INITIATING INFANT FORMULA FOLLOWUP ACTIVITIES

FDA's policy states that complaints involving infant formula or baby food require immediate followup on a high-priority basis.[54] However, FDA did not always adhere to this policy and did not always document its rationale for delaying followup activities. We reviewed 62 Abbott facility consumer complaints.[55] As of January 2023, FDA classified the 40 infant formula complaints as surveillance next inspection instead of immediate followup. For these 40 complaints (about 65 percent of the consumer complaints we reviewed), it took FDA an average of 188 days (130 business days) to conduct a followup investigation activity after the complaint was recorded in FDA's complaint system.[56] For the remaining 18 complaints, FDA classified the complaints as immediate followup and conducted a followup investigation activity within, on average, 9 days (6 business days) after the complaint was recorded in FDA's complaint system.

From our review of the infant formula complaints, it was not apparent why FDA classified the 40 complaints to be followed up at the next surveillance inspection because its policy states

[53] On Mar. 28, 2022, FDA completed an HHE related to the Abbott facility recall. An HHE is an evaluation of the health hazard presented by a product being recalled or considered for recall, which includes specific factors such as whether any disease or injuries have already occurred from the use of the product.

[54] SOP-000544 (Revision 00) § 6.1.3.

[55] In total, we reviewed 63 consumer complaints. One of the 63 consumer complaints was recorded by FDA prior to FDA's implementation of its consumer complaint SOPs. For the one complaint that is not included in our calculations, FDA did not classify the complaint as "immediate followup," and it took FDA 725 days to review the complaint during the next scheduled inspection. For 4 of the remaining 62 complaints, FDA did not classify the complaint, closed the complaint without further investigation in accordance with its policies and procedures, or referred the complaint to its Office of Criminal Investigations. Of the 58 Abbott facility consumer complaints, 4 were recorded on or prior to the recall (Feb. 17, 2022), and the remaining 54 Abbott facility consumer complaints were recorded after the date of the recall.

[56] Followup investigation activities could include an investigation, sample collection, or a review of the complaint during the next inspection.

that complaints involving infant formula or baby food require immediate followup. However, we noted that FDA had implemented additional consumer complaint followup guidance related to the Abbott infant formula recall. This included collecting infant formula samples for certain unopened, nonrecalled infant formula from the Abbott facility. The guidance also indicated that FDA would not collect samples of recalled infant formula or opened nonrecalled formula. This may have contributed to FDA classifying some of the 40 infant formula complaints as surveillance next inspection, which delayed FDA's response to these complaints. Because FDA did not clearly and consistently document its rationale for assigning initial dispositions to the Abbott infant formula consumer complaints, it could not demonstrate that the 40 complaints met the intent of its policy to conduct immediate followup on a high-priority basis. FDA may need to clarify its consumer complaint policy for infant formula followup and clearly document in its complaint system the rationale for assigning initial dispositions.

THE FDA INSPECTION SCHEDULES ARE TOO PREDICTABLE

FDA has not assessed the inspection scheduling process to identify risks. At the beginning of each fiscal year, FDA creates an infant formula inspection memo that lists all infant formula manufacturers subject to a surveillance inspection and proposed inspection start dates. The memo is distributed to FDA field offices responsible for conducting the inspections.

Based on our analysis of the infant formula inspection memos for FY 2019 through FY 2022, we identified 20 infant formula facilities that had inspections scheduled during all 4 fiscal years. For 19 of the 20 facilities, FDA planned to conduct the inspection during the same 2-week span of the same month annually. For the final facility, FDA planned to conduct the inspection during September for FY 2019 through FY 2021 but planned to conduct the inspection during August for FY 2022.

According to FDA, infant formula inspections were scheduled in this manner to ensure that inspections occurred on an annual basis, approximately every 12 months. By scheduling inspections at facilities during the same week each year, FDA is not responding to the risks that a facility could predict and prepare for an FDA inspection. For example, according to a *Politico* article, a former supervisor at the Abbott facility stated, "The plant would prep heavily before audits . . .. The plant basically turned into a movie set where only things the higher ups wanted the FDA to see were seen."[57] FDA stated that it has modified its approach for FY 2023 inspections to avoid planning inspections in the same month of the previous year when possible.

Based on the information provided in this report, FDA may need to formalize a policy that ensures that a manufacturer is not able to reliably predict when its annual inspections will occur.

[57] Helena Bottemiller Evich, "'A movie set': Former supervisor at baby formula plant says flaws were hidden," *Politico*, Aug. 4, 2022. Available online at https://www.politico.com/news/2022/08/04/baby-formula-plant-flaws-hidden-00049721. Accessed on May 20, 2024.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed the February 2021 and October 2021 complaints that a whistleblower made related to the Abbott facility during our audit period of January 1, 2019, through June 30, 2022.[58] We also reviewed 48 infant formula consumer complaints involving life-threatening illness or death among infants who consumed infant formula manufactured at the Abbott facility during this time, along with 15 randomly selected infant formula consumer complaints that were not life threatening or had no adverse event and 15 randomly selected infant formula adverse event reports.

We assessed FDA's internal written policies and procedures for consumer complaint and adverse event report processing, whistleblower complaints, infant formula facilities, infant formula recalls, and inspection scheduling. In addition, we reviewed standards in GAO's *Standards for Internal Control in the Federal Government.* We limited our review of FDA's internal controls to those related to our audit objective.

We performed our audit work from June 2022 through October 2023.

METHODOLOGY

To accomplish the audit objective, we:

- reviewed Federal laws and regulations; FDA's internal written policies and procedures; and industry guidance FDA published regarding complaints, whistleblowers, infant formula, recalls, and inspections of infant formula facilities;

- interviewed FDA personnel responsible for recording and processing complaints, scheduling inspections, conducting inspections, and assisting manufacturers in initiating recalls;

- reviewed FDA's process for inspection scheduling of infant formula manufacturers;

- obtained and reviewed whistleblower complaints FDA received regarding the Abbott facility;

- reviewed the EIR for the September 2019, September 2021, and January 2022 Abbot facility inspections;

[58] An April 2022 whistleblower complaint from a separate whistleblower was identified and reviewed through the 15 randomly selected infant formula consumer complaints that were not life threatening or had no adverse event.

- determined whether FDA conducted its 2022 Abbott facility inspection in a timely manner;

- obtained and reviewed consumer and whistleblower complaints, policies and procedures, and records of discussion related to the initiation of the February 17, 2022, and February 28, 2022, Abbott recalls;

- reviewed information from the CAERS database to determine whether adverse event reports were sufficient for FDA to trace products to a specific manufacturer;

- selected for review consumer complaints and adverse events using the following methodology:

    - selected for review all 48 Abbott facility infant formula consumer complaints with a complaint result of "death" or "life-threatening injury/illness,"
    - created a sampling frame of 119 Abbott facility infant formula consumer complaints with a complaint result of "non-life-threatening injury/illness" or no adverse event and randomly selected (using OIG statistical software) 15 consumer complaints with a complaint result of "non-life-threatening injury/illness" or no adverse event, and
    - created a sampling frame of 433 infant formula adverse event reports and randomly selected (using OIG statistical software) 15 adverse event reports;

- determined, for consumer complaints and adverse events:

    - whether CFSAN forwarded the adverse event report to OEO and the time it took to forward the adverse event to OEO (for adverse event reports);
    - whether OEO forwarded the adverse event report to ORA and the time it took to forward the adverse event to ORA (for adverse event reports);
    - whether ORA notified the OEO of the complaint and the time it took to notify OEO (for consumer complaints);
    - the time it took FDA to determine the initial disposition; and
    - the time it took FDA to complete the followup actions including inspections, investigations, and sample collection;

- obtained and reviewed FDA funding and staff levels for individuals assigned to CFSAN's infant formula oversight activities and ORA's infant formula inspections for FY 2019 through FY 2022;

- obtained and reviewed information related to FDA's consent decree with Abbott and FDA's ongoing presence at the Abbott Sturgis facility as a result of the February 2022 inspection;

- reviewed FDA authority to require reporting positive *Cronobacter* results in facilities;

- reviewed FDA actions to determine whether the agency took appropriate steps for a potential infant formula supply chain shortage based on the Abbott recall; and

- discussed the results of our review with FDA officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

APPENDIX B: FEDERAL LAW, REGULATION, AND GUIDANCE

FEDERAL CRITERIA

Federal Food, Drug, and Cosmetic Act

Section 412 (21 U.S.C. § 350a(e)): If the manufacturer of an infant formula has knowledge which reasonably supports the conclusion that an infant formula which has been processed by the manufacturer and which has left an establishment subject to the control of the manufacturer - (A) may not provide the nutrients required by subsection (i), or (B) may be otherwise adulterated or misbranded, the manufacturer shall promptly notify the Secretary of such knowledge. If the Secretary determines that the infant formula presents a risk to human health, the manufacturer shall immediately take all actions necessary to recall shipments of such infant formula from all wholesale and retail establishments, consistent with recall regulations and guidelines issued by the Secretary. For purposes of paragraph (1), the term "knowledge" as applied to a manufacturer means (A) the actual knowledge that the manufacturer had, or (B) the knowledge which a reasonable person would have had under like circumstances or which would have been obtained upon the exercise of due care.

Federal Regulations

21 CFR section 107.200: When the Food and Drug Administration determines that an adulterated or misbranded infant formula presents a risk to human health, a manufacturer shall immediately take all actions necessary to recall that formula, extending to and including the retail level, consistent with the requirements of this subpart.

GAO's *Standards for Internal Control in the Federal Government*

Section 3.03: Management develops an organizational structure with an understanding of the overall responsibilities and assigns these responsibilities to discrete units to enable the organization to operate in an efficient and effective manner, comply with applicable laws and regulations, and reliably report quality information. Based on the nature of the assigned responsibility, management chooses the type and number of discrete units, such as divisions, offices, and related subunits.

Section 10.03: *Accurate and timely recording of transactions* - Transactions are promptly recorded to maintain their relevance and value to management in controlling operations and making decisions. This applies to the entire process or life cycle of a transaction or event from its initiation and authorization through its final classification in summary records. In addition, management designs control activities so that all transactions are completely and accurately recorded.

Section 12.01: Management should implement control activities through policies.

Section 12.02: Management documents in policies the internal control responsibilities of the organization.

Section 12.03: Management documents in policies for each unit its responsibility for an operational process's objectives and related risks, and control activity design, implementation, and operating effectiveness. Each unit, with guidance from management, determines the policies necessary to operate the process based on the objectives and related risks for the operational process. Each unit also documents policies in the appropriate level of detail to allow management to effectively monitor the control activity.

Section 13.01: Management should use quality information to achieve the entity's objectives.

Section 13.03: Management identifies information requirements in an iterative and ongoing process that occurs throughout an effective internal control system. As change in the entity and its objectives and risks occurs, management changes information requirements as needed to meet these modified objectives and address these modified risks.

Section 13.05: Management processes the obtained data into quality information that supports the internal control system. This involves processing data into information and then evaluating the processed information so that it is quality information. Quality information meets the identified information requirements when relevant data from reliable sources are used. Quality information is appropriate, current, complete, accurate, accessible, and provided on a timely basis. Management considers these characteristics as well as the information processing objectives in evaluating processed information and makes revisions when necessary so that the information is quality information. Management uses the quality information to make informed decisions and evaluate the entity's performance in achieving key objectives and addressing risks.

Section 14.02: Management communicates quality information throughout the entity using established reporting lines. Quality information is communicated down, across, up, and around reporting lines to all levels of the entity.

Section 14.03: Management communicates quality information down and across reporting lines to enable personnel to perform key roles in achieving objectives, addressing risks, and supporting the internal control system. In these communications, management assigns the internal control responsibilities for key roles.

Section 14.04: Management receives quality information about the entity's operational processes that flows up the reporting lines from personnel to help management achieve the entity's objectives.

FDA Policies and Procedures

FMD 119, section 4.1.1: Consumer complaints are entered into the FACTS Consumer Complaint database by the consumer complaint coordinator in the District receiving the complaint. All consumer complaints involving FDA-regulated products and problems must be entered into FACTS. Every effort should be made to accurately complete each FACTS data field. Information in these fields is important when reviewing and evaluating complaints. It is critical for use in retrieving, tracking, trending, and comparing consumer complaints.

SOP-000544 (Revision 00) § 3.K.9: Consumer complaint coordinators are responsible to ensure all complaint followup operations are linked to the complaint in FACTS.

SOP-000544 (Revision 00) § 6.1.3: All complaints involving either infant formula or baby food are to be investigated on a high-priority basis.

SOP-000544 (Revision 00) § 6.1.5: The consumer complaint coordinator enters all complaints received in FACTS under the geographical location district abbreviation and disposition complaints accordingly.

SOP-000108 (Revision 06) § 1: The purpose of quality factor checklists (QFCs) is to identify issues with ORA's products and to implement improvements. Quality factors include critical issues which, if missed, could result in product rejection by the customer. QFCs can also be used to determine trends in the quality of the products, and to help ORA offices detect issues with their products before and after release. QFCs are tools for quality control of ORA's work products, processes, and services. This standard operating procedure (SOP) establishes the responsibilities and methodologies for developing and using QFCs, which serve as tools for determining the "fitness for use" of work products. Each respective checklist contains a set of standardized requirements, based on documentation (e.g., policy, SOP, standard) for which products are reviewed. Each checklist is designed to be an effective tool helping to ensure the highest levels of quality and provide opportunities for continual improvement.

SOP-000108 (Revision 06) § 6.2: QFCs have five main uses:[59]

- Quality Control: Management, quality system managers (QSMs), or designated personnel may use the QFCs for quality control of products, processes, or services before they are released.

- Quality Assurance: Management, QSMs, or designated personnel may use the data from QFCs for quality assurance purposes. For example, data from QFC trending may be used for identifying issues or opportunities in the product creation process.

[59] In the report, we combine quality assurance and audits. Therefore, we say the QFCs have four main uses: quality control, quality assurance/audits, job aid/self-check, and training.

- Audits: QFCs may be used as part of an internal audit. Refer to SOP-000365 - Internal Audits SOP for more details.

- Job Aid/Self-Check: Employees may use QFCs to review their own products, processes, or services.

- Training: QFCs may be used as part of a training program (e.g., for re-training or for new hires).

IOM § 5.2.1: Prior to the start of any inspection or investigation, you should conduct a number of activities. These will differ based on whether this is an inspection or an investigation. You should review the establishment's factory jacket (if one exists), consumer complaints, and registration and listing (if applicable) information. The purpose of this review is to determine the location of the establishment and obtain an overview of the establishment's operations and products as well as an understanding of their compliance history. Consumer complaint review will also determine if there are any complaints with open assignments, or with the status surveillance next inspection that need to be closed. You should also review the establishment factory jacket to determine if there were any prior safety issues noted, e.g., documented investigator safety incidents or whether any specific personal protective equipment is needed prior to the start of the inspection. If there has been a past personal safety incident, you should discuss with your supervisor and develop a Situational Plan prior to the start of the inspection.[60, 61]

Work Instruction for CAERS Complaints: Members of the CAERS team review each complaint and if they determine that it warrants further followup, they forward the complaint to the NCCC. The NCCC reviews the complaint. If it warrants further followup, determine the home district based on the State of residence of the complainant and forward the complaint to the corresponding consumer complaint coordinator.

FDA Guidance

NCCC Position Description: This position serves as a specialist for the Food and Drug Administration (FDA), Office of the Commissioner (OC), Office of Crisis Management (OCM), Office of Emergency Operations (OEO) in the area of emergency coordination, epidemiology, bacterial, viral and parasitic infections, and injury/disease investigation coordination. The emergency coordination often takes place outside regular duty hours. This position provides

[60] IOM (2021 version), chapter 5, § 5.2.1.

[61] FDA's policies do not define "open assignment." Our understanding is that an open assignment is any assignment (which could include an investigation or sample collection) that is not marked "closed." FDA policies state that the surveillance next inspection disposition should be used when immediate action is not warranted on the complaint; however, the complaint still requires investigation upon the next inspection at the firm. This inspection will occur according to the appropriate scheduled interval.

professional investigations coordination. Serves as Late Duty Officer for agency after-hours contact. Major duties include maintaining situational awareness of activities, events, and incidents, and provides recommendations to other staff members regarding appropriate information and advice to provide to FDA District Office staff. Considers, identifies, and assists in the evaluation of possible sources of contamination of food, drugs, cosmetics, devices, biologics, and tobacco products - such as new materials, water and air supplies, processing operations and equipment, employees, environment and plant facilities, and methods of identifying and eliminating the vectors of contamination.

Resiliency Roadmap for FDA Inspectional Oversight: In March 2020, at the onset of the pandemic, FDA reserved inspections for mission-critical issues and temporarily postponed all routine domestic and foreign surveillance facility inspections. Inspections identified as mission critical continued across all FDA-regulated commodities regardless of physical site location, foreign and domestic. Factors determining mission-critical inspections:

- Product received breakthrough therapy or regenerative medicine advanced therapy designation.

- Product is used to treat a serious disease or medical condition and there is no substitute.

- Product requires followup due to recall, or there is evidence of serious adverse events or outbreaks of a foodborne illness.

- Product is related to FDA's COVID-19 response (e.g., drug shortages).

APPENDIX C: HHS OFFICES INVOLVED IN INFANT FORMULA OVERSIGHT

FDA Office of Regulatory Affairs: ORA is responsible for conducting inspections of infant formula facilities based on annual schedules CFSAN provides. In some cases, ORA is also responsible for receiving and recording certain types of complaints. ORA, in coordination with CFSAN, is responsible for investigating complaints.

FDA Center for Food Safety and Applied Nutrition: CFSAN is responsible for reviewing infant formula premarket applications for potential new manufacturers, reviewing infant formula manufacturing changes, providing feedback to manufacturers regarding potential problems, providing subject matter expertise around nutrition affecting health, providing support in the evaluation of adverse event reports and complaints, and providing support in inspection planning and prioritization. In some cases, CFSAN is also responsible for receiving and recording complaints. CFSAN and ORA collaborate to assist manufacturers in initiating voluntary infant formula recalls.

FDA Office of Food Policy and Response: OFPR provides executive leadership, direction, and coordination over policy initiatives involving food safety modernization activities and human food safety programs. It also coordinates the oversight of food-related outbreak responses, tracebacks, recalls, and communication to stakeholders involving threats to human health.

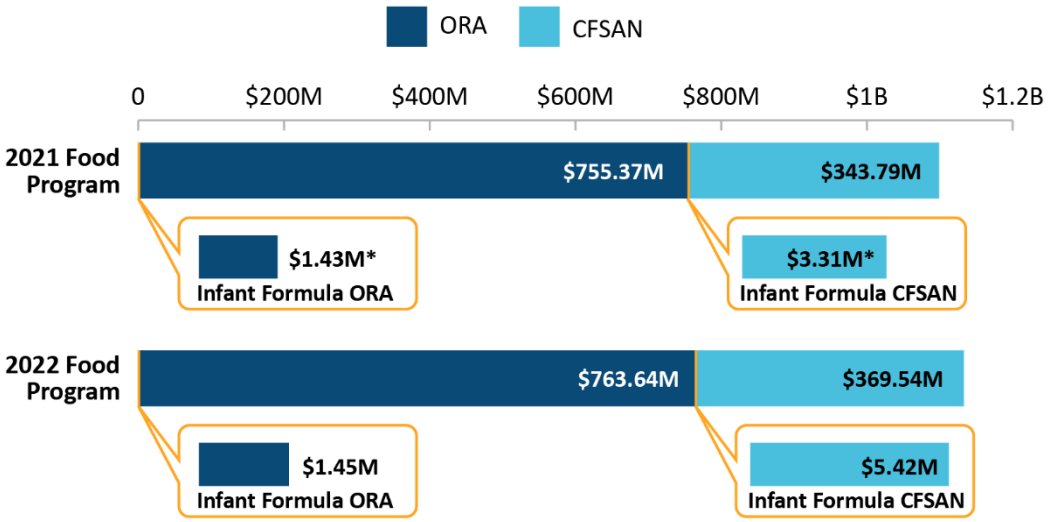
FDA Office of Operations: The Office of Operations, through OEO, is responsible for managing consumer complaints on a national level. OEO is also responsible for receiving whistleblower complaints sent from DOL.

Centers for Disease Control and Prevention: CDC is responsible for receiving and testing clinical sample results for *Cronobacter*. If testing reveals the presence of *Cronobacter*, CDC works with FDA to investigate the case.

APPENDIX D: FDA BUDGET AND STAFFING INFORMATION FOR INFANT FORMULA PROTECTION

According to FDA, the total ORA food safety and CFSAN budget during FY 2021 and FY 2022 was $1.10 billion and $1.13 billion, respectively.[62] In FY 2021, the infant formula protection budget was 0.43 percent ($4.73 million) of the total food budget. In FY 2022, the infant formula protection budget was 0.61 percent ($6.87 million) of the total food budget. (See Figure 3.)

Figure 3: FDA Budget for Infant Formula Protection

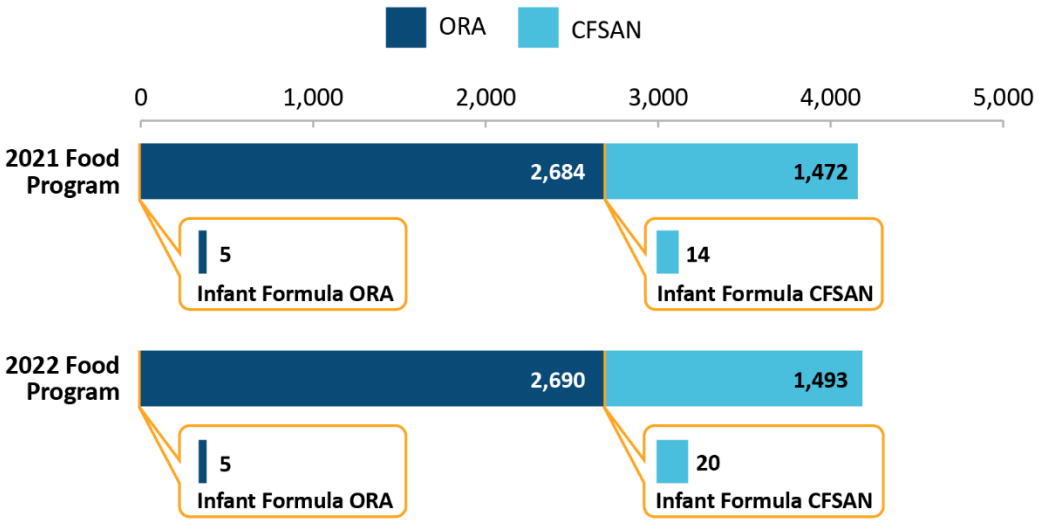


* The FY 2021 infant formula protection budget adds up to $4.74 million instead of $4.73 million based on rounding differences.

Within ORA and CFSAN, FDA has a small group dedicated to the oversight of infant formula. This group comprised 19 full-time employees (FTEs) from ORA and CFSAN for FY 2021 and 25 FTEs for FY 2022. (See Figure 4 on the next page.)

[62] FDA's 2021 $1.10 billion food budget comprised $755.37 million related to ORA inspections and $343.79 million related to CFSAN's oversight. FDA's FY 2022 $1.13 billion food budget comprised $763.64 million related to ORA inspections and $369.54 million related to CFSAN's oversight.

Figure 4: FDA Staffing for Infant Formula Protection



FDA stated that ORA conducts infant formula inspections and CFSAN reviews manufacturers' notifications that ensure that manufacturers comply with certain labeling, nutrient content, manufacturer quality control procedures (to assure the nutrient content of infant formulas), and company recordkeeping and reporting requirements. According to FDA officials, FDA requested and, during FY 2022, was granted $1.12 million to hire four FTEs for its infant formula review team.[63] In addition to the four new FTEs, CFSAN's Office of Nutrition and Food Labeling reassigned two FTEs from the overall nutrition and food labeling staff to work on infant formula issues while the four new FTEs were onboarded and trained.

Table 1: Budget*†

Budget Authority	FY 2019	Percent Change	FY 2020	Percent Change	FY 2021	Percent Change	FY 2022
CFSAN Infant Formula	$2,377	21%	$2,869	15%	$3,308	64%	$5,420
ORA Infant Formula	$1,375	2%	$1,400	2%	$1,425	2%	$1,450
Total	**$3,752**	14%	**$4,269**	11%	**$4,733**	45%	**$6,870**
CFSAN Food Program	$334,412	2%	$341,966	1%	$343,789	7%	$369,537
ORA Food Program	$732,604	2%	$746,915	1%	$755,371	1%	$763,639
Total	**$1,067,016**	2%	**$1,088,881**	1%	**$1,099,160**	3%	**$1,133,176**
Infant Formula Percentage of Food Program Total	**0.35%**		**0.39%**		**0.43%**		**0.61%**

* Budget data provided by FDA officials.
† Funding is represented in millions.

[63] As of the end of 2022, CFSAN was in the process of onboarding the additional staff for its infant formula review team.

Table 2: Staffing*

Staffing (Employees and Contractors)	FY 2019	Percent Change	FY 2020	Percent Change	FY 2021	Percent Change	FY 2022
CFSAN Staffing Infant Formula	12	8%	13	8%	14	43%	20
ORA Staffing Infant Formula	5	0%	5	0%	5	0%	5
Total	**17**	**6%**	**18**	**6%**	**19**	**32%**	**25**
CFSAN Staffing Food Program	1,406	2%	1,441	2%	1,472	1%	1,493
ORA Staffing Food Program	2,714	-1%	2,678	0%	2,684	0%	2,690
Total	**4,120**	**0%**	**4,119**	**1%**	**4,156**	**1%**	**4,183**
Infant Formula Percentage of Food Program Total	**0.41%**		**0.44%**		**0.46%**		**0.60%**

* Staffing data provided by FDA officials.

APPENDIX E: FDA REPORTED *CRONOBACTER* ILLNESSES AND DEATHS AND FDA'S INFANT FORMULA TESTING PROGRAM

FDA REPORTED *CRONOBACTER* ILLNESSES AND DEATHS

According to FDA, there are no laws or regulations mandating postmarket adverse event reporting for infant formula, though FDA encourages voluntary reporting of adverse experiences associated with these products. Additionally, FDA receives complaints or reports of adverse events, not verified cases of illness.

According to FDA, consumer complaints were included in the Abbott facility *Cronobacter* investigation case counts when the complaint involved a medically confirmed *Cronobacter* illness and the infant consumed Abbott's recalled product prior to illness. Although FDA reported four hospitalizations, including two infant deaths, in its case counts related to the Abbott facility *Cronobacter* investigation, FDA also stated that it has not been able to "definitively link" any of the illnesses or deaths to the Abbott facility. Making a definitive link to the Abbott facility involves performing whole genome sequencing, which involves comparing *Cronobacter* bacteria samples taken from sick infants to *Cronobacter* samples found at the Abbott facility to determine if there is any relation.[64] According to FDA, as of April 10, 2023, FDA has analyzed 45 *Cronobacter* samples related to the Abbott facility investigation. FDA stated that there has been no definitive links between the *Cronobacter* strains collected from products produced at the Abbott facility or environmental samples taken from the Abbott facility and *Cronobacter* samples identified in sick infants.

During our audit period, FDA received 167 consumer complaints related to the Abbott facility. Of the 167 complaints, 148 complaints (approximately 89 percent) were recorded by FDA on or after the first Abbott facility recall was announced, and 19 (approximately 11 percent) were recorded prior to February 17, 2022. Four of the 167 complaints (including 2 deaths) were reported on FDA's website because the complaint involved a medically confirmed *Cronobacter* illness, and the infant consumed Abbott's recalled product prior to becoming ill. The other 163 complaints were related to the Abbott facility because FDA determined that the product was manufactured at the Abbott facility, but the complaints were not related to the Abbott facility *Cronobacter* investigation. According to FDA, the complaints did not meet the case definition for inclusion in the *Cronobacter* investigation case counts. In addition, FDA stated that the 15 additional deaths were not linked to the Abbott facility *Cronobacter* investigation or reported

[64] Whole genome sequencing reveals an organism's complete DNA makeup, which enables a better understanding of variations both within and between species. FDA is using this technology to perform basic foodborne pathogen identification during foodborne illness outbreaks and applying it in novel ways that have the potential to help reduce foodborne illnesses and deaths over the long term, both in the United States and abroad. The most basic application of this technology to food safety is using it to identify pathogens isolated from food or environmental samples. These can then be compared to clinical isolates from patients. If the pathogens found in the food or food production environment match the pathogens from the sick patients, a reliable link between the two can be made, which helps define the scope of a foodborne illness outbreak.

by FDA because an FDA medical officer reviewed the complaints and found that *Cronobacter* was not confirmed or suspected as the cause of death for any of the listed reports.[65]

We also noted that FDA distributed finished product sampling guidance to the CAERS coordinator and the NCCC on February 18, 2022, but we determined that it was not conducive to identifying sick children who consumed *Cronobacter*-contaminated infant formula from the Abbott facility. Specifically, the guidance described sampling unopened, nonrecalled product from the Abbott facility from complainants who had sick infants. The guidance stated that FDA was not asking to sample any recalled or open products. The purpose of this guidance was to potentially identify other Abbott products that were not currently subject to the recall; however, this guidance would potentially prevent FDA from linking sick infants to *Cronobacter*-contaminated infant formula from the Abbott facility.

FDA'S INFANT FORMULA TESTING PROGRAM

Outside of inspections and complaint followups, FDA tests infant formula for pathogens including *Cronobacter* and *Salmonella* through various directed oversight activities and through a testing program known as the Laboratory Flexible Funding Model (LFFM) Cooperative Agreement Program. According to FDA, directed oversight activities refer to inspections and sampling assignments that are limited in scope and focus on specific areas or issues. FDA stated that it may sample and test infant formula for pathogens through directed oversight activities as warranted to address a public health issue or to collect samples under other domestic or import compliance programs. FDA also launched a coordinated national laboratory response to the Abbott recall through the LFFM Cooperative Agreement Program.[66] Under this program, FDA laboratories and LFFM laboratories—including the Maryland Department of Health Laboratories Administration, the Ohio Department of Agriculture, and the West Virginia Department of Agriculture—conduct testing of powdered infant formula samples for *Cronobacter* both when FDA receives consumer complaints and on behalf of other States that are unable to perform this analysis.

[65] One of the 15 complaints involved a serious injury/illness, not an infant death. It is included here due to a data-quality issue as mentioned in the second bullet under the section in this report titled "FDA Did Not Have Adequate Policies and Procedures To Identify and Correct Infant Formula Complaint Data Inaccuracies."

[66] FDA, "Laboratory Flexible Funding Model Cooperative Agreement Program: What is the Laboratory Flexible Funding Model?" Available online at https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/grants-and-cooperative-agreements/laboratory-flexible-funding-model-cooperative-agreement-program. Accessed on May 20, 2024.

During the audit period, FDA collected and (in some cases, in coordination with LFFM laboratories) tested 170 infant formula samples for *Cronobacter*.[67] One sample collected from an infant formula manufacturer tested positive for *Cronobacter* on July 6, 2021.

[67] From Jan. 1, 2019, through June 30, 2022, the Maryland Department of Health was the only laboratory under the LFFM that tested infant formula. The Maryland Department of Health tested 61 samples during the audit period.

APPENDIX F: FDA'S 2022 ACTIVITIES AT THE ABBOTT FACILITY AFTER THE CONSENT DECREE

During the six inspections since the January 2022 inspection, FDA conducted the following activities:

- Beginning May 28, 2022 (2 days at facility): FDA initiated an inspection to observe Abbott's independent expert, and Abbott's staff conducted environmental swabbing and assessed the facility's implementation of corrective actions as it prepared to resume operations.

- Beginning June 16, 2022 (5 days at facility): FDA initiated a followup inspection to assess damages after a storm caused flooding at the Abbott facility. Abbott management notified FDA of the storm on June 15, 2022. FDA investigators arrived at the facility to assess damages and verify that the damage did not impact stored finished product. Investigators also observed the facility's cleaning cycles and swabbing events and discussed the repairs made due to the flood.

- Beginning August 8, 2022 (26 days at facility): FDA initiated a followup inspection to verify Abbott's root cause analysis activities in response to its recent positive and presumptive positive *Cronobacter* findings in finished product samples.

- Beginning September 28, 2022 (4 days at facility): FDA initiated an inspection to review consumer complaints received after the Abbott recall press release.

- Beginning October 11, 2022 (6 days at facility): FDA initiated an inspection to observe the restart of dryers after the annual maintenance shutdown.

- Beginning November 14, 2022 (8 days at facility): FDA initiated a comprehensive establishment inspection after the consent decree, including environmental monitoring.

APPENDIX G: TIMELINE OF EVENTS FOR FDA INFANT FORMULA RECALL

February 19, 2021: DOL forwarded a whistleblower complaint related to the Abbott facility to FDA. According to FDA, it did not identify and investigate this whistleblower complaint at that time.

September 20, 2021 – September 24, 2021: FDA conducts a surveillance inspection at the Abbott facility.

September 20, 2021: FDA receives a consumer complaint related to a case of *Cronobacter* in a 24-day-old infant.

October 21, 2021: FDA receives a complaint from a whistleblower electronically. The complaint was from the same whistleblower and contained similar allegations to the February 2021 whistleblower complaint. FDA begins planning for an inspection at the Abbott facility.

November 4, 2021: FDA staff discuss the October 2021 whistleblower complaint with FDA's Office of Criminal Investigations.

November 8, 2021: FDA discusses the October 2021 whistleblower complaint with the investigator and national expert who inspected the Abbott facility in September 2021.

November 17, 2021: FDA receives a consumer complaint of a *Salmonella* illness potentially associated with the Abbott facility. FDA and CDC rule that this is unrelated to the Abbott facility.

December 1, 2021: FDA receives a consumer complaint of a *Cronobacter* infant death potentially associated with the Abbott facility. The date of illness onset was November 20, 2021. Formula samples were collected but were negative for *Cronobacter*.

December 7, 2021: FDA requests to interview the October 2021 whistleblower. Due to scheduling limitations, the interview was scheduled to take place on December 22, 2021.

December 22, 2021: FDA interviews the October 2021 whistleblower.

December 30, 2021: FDA contacts the Abbott facility to inform them that it will conduct an inspection beginning on January 3, 2022. Abbott informs FDA of a COVID-19 outbreak at the facility. FDA agrees to delay the inspection.

January 11, 2022: FDA receives a consumer complaint of a *Cronobacter* illness. The date of illness onset was December 18, 2021. Samples were collected but were negative for *Cronobacter*.

January 27, 2022: FDA contacts Abbott to announce its intention to proceed with the inspection despite the continued COVID-19 outbreak at the Abbott facility.

January 31, 2022: FDA begins its inspection at the Abbott facility.

February 7, 2022: FDA's environmental swabbing during the Abbott facility inspection suggests the potential presence of *Cronobacter*.

February 14, 2022 – February 15, 2022: Environmental swabs are confirmed positive for *Cronobacter*.

February 17, 2022: Abbott voluntarily recalls certain products that were manufactured at the Abbott facility.

February 24, 2022: FDA receives a consumer complaint of a *Cronobacter* infant death potentially associated with the Abbott facility and to a product that was not subject to the original recall. The date of illness onset was January 4, 2022. Samples were collected but were negative for *Cronobacter*.

February 28, 2022: Abbott voluntarily expands the recall to include one lot of a product not covered under the original recall.

APPENDIX H: EVENTS AFTER THE FEBRUARY 2022 RECALL

As of June 2023, we are aware of: (1) two reports, the first report related to the challenges that led to the infant formula supply shortage, and the second report related to FDA's human food program; (2) several investigations into Abbott, including investigations by the Department of Justice, the Securities and Exchange Commission, and the Federal Trade Commission; and (3) four other infant formula recalls announced by FDA due to *Cronobacter.*

FDA REQUESTED REVIEWS

The FDA Commissioner requested two reviews, including: (1) an FDA internal review to identify the challenges encountered in addressing the circumstances that eventually led to an infant formula supply shortage and (2) a Reagan-Udall Foundation review of the FDA human foods program with the aim of strengthening FDA's food-related regulatory role.[68, 69] The Reagan-Udall Foundation review was meant to provide recommendations that would equip FDA to carry out its regulatory responsibilities, strengthen its relationships with State and local governments, and secure the Nation's food supply for the future.

In September 2022, FDA issued an internal review report titled *FDA Evaluation of Infant Formula Response.* In its report, FDA identified 15 findings and provided recommendations related to 5 major areas of need. Specifically, FDA's report stated that it needs to:

- modernize data systems,
- optimize its emergency response capabilities,
- strengthen its food workforce,
- improve oversight to focus on industry accountability, and
- work with engaged stakeholders to close scientific gaps and build a more robust regulatory program.

In December 2022, the Reagan-Udall Foundation issued a report titled *Operational Evaluation of the FDA Human Foods Program*. The report identified findings and provided recommendations related to FDA's culture, structure, resources, and authorities.

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[68] FDA, *FDA Evaluation of Infant Formula Response,* September 2022. Available online at https://www.fda.gov/media/161689/download. Accessed on May 20, 2024.

[69] The Reagan-Udall Foundation for the FDA is an independent 501(c)(3) organization created by Congress to advance FDA's mission. The Reagan-Udall Foundation submitted its report, *Operational Evaluation of the FDA Human Foods Program*, on Dec. 6, 2022. Available online at: https://reaganudall.org/operational-evaluation-fdas-human-foods-programs. Accessed on May 20, 2024.

INVESTIGATIONS INTO ABBOTT

According to Abbott's 2022 annual report, in November 2022, Abbott learned that the Department of Justice, through the U.S. Attorney's Office for the Western District of Michigan, was conducting a criminal investigation related to Abbott's manufacturing of infant formula. In December 2022, Abbott received a subpoena from the Security and Exchange Commission's Enforcement Division requesting information relating to Abbott's powdered infant formula business and related public disclosures. In January 2023, Abbott received a civil investigative demand from the Federal Trade Commission seeking information in connection with its investigation of companies that participate in bids for infant formula contracts through the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). In addition, multiple civil lawsuits have been filed against Abbott regarding Abbott's manufacturing of certain powdered infant formula products.

RECENT INFANT FORMULA *CRONOBACTER* RECALLS

According to FDA, *Cronobacter* is a pathogen found naturally in the environment that can enter manufacturing facilities and home environments on hands, shoes, and other contaminated surfaces. *Cronobacter* is especially good at surviving in dry foods, including powdered infant formula. For most people *Cronobacter* is harmless, but it can be life threatening for infants younger than 2 months, infants who are born prematurely, and infants who have weakened immune systems. FDA stated that *Cronobacter* infections are not a nationally notifiable condition, meaning that State health departments may not report *Cronobacter* cases to CDC as a matter of course. Furthermore, CDC reported that only two States, Minnesota and Michigan, require *Cronobacter* reporting to the State health department. Therefore, it is difficult to track *Cronobacter* cases. FDA also stated that there is not a robust database of historic *Cronobacter* genetic sequences available with which to compare new cases to determine a genetic connection with a previously detected strain.

According to FDA, the Council of State and Territorial Epidemiologists voted to elevate *Cronobacter* to a nationally notifiable disease on June 29, 2023, and *Cronobacter* notifications were planned to take effect the beginning of 2024, at the decision of each State. According to FDA, CDC and the States are responsible for the determination of a case definition, identification of cases, and verification of illnesses and deaths. FDA works with CDC and, when referring to illnesses or deaths, FDA generally uses hospitalization and death counts verified by CDC.

Since the Abbott facility recalls in February 2022, FDA has announced four other infant formula recalls due to *Cronobacter* as of June 2023.[70] From January 1, 2019, through February 16, 2022, FDA did not report any infant formula recalls related to *Cronobacter* contaminations.

[70] On Dec. 11, 2022, ByHeart announced a voluntary recall of five batches of ByHeart Whole Nutrition Infant Formula due to the potential for cross-contamination with *Cronobacter*. On Feb. 20, 2023, Reckitt announced a voluntary recall of two select batches of ProSobee 12.9 oz. Simply Plant-Based Infant Formula due to a possibility of cross-contamination with *Cronobacter*. On Mar. 17, 2023, Perrigo Company, plc, announced a voluntary recall of certain lots of Gerber Good Start SoothePro™ Powdered Infant Formula due to the potential presence of *Cronobacter.* On May 13, 2023, Associated Wholesale Grocers, Inc. (AWG) released an additional notice for the previously recalled Perrigo product that AWG distributed to its Nashville Division retailers.

APPENDIX I: ADDITIONAL INFORMATION ON FDA ACTIONS RELATED TO INFANT FORMULA INSPECTIONS

During our audit, we noted that FDA took some action during the Abbott facility inspections and followed up on inspectional observations in accordance with Federal regulations and its internal policies and procedures. Specifically, FDA:

- reviewed the Abbott facility's testing and production records during the 2019, 2021, and 2022 inspections;
- reviewed documentation related to product destruction during the Abbott facility inspections;
- reviewed certain information in Abbott's food safety plan during the 2019, 2021, and 2022 inspections; and
- followed up on inspectional observations identified during the 2019 and 2021 inspections.

PRODUCTION RECORDS

FDA requested and reviewed production and testing records during the September 2019, September 2021, and January 2022 inspections. According to FDA officials, during a routine inspection, FDA typically will review five to seven batch records. FDA officials stated that they typically focus on one product, such as a product FDA may not have inspected in a while or a product that is brand new. FDA's establishment inspection report (EIR) indicates that a batch record consists of a master work order, which outlines all production steps, including ingredient weighing, liquid base processing, pasteurization and spray drying, blending, and filling/packaging; a copy of the finished product label; and in-process and finished product testing results. From our review of the EIRs, FDA reviewed 10 batch records related to Similac Alimentum, Provamin, and Calcilo XD products in 2019; 5 batch records related to Similac Alimentum products in 2021; and 16 batch records related to Similac powdered infant formula products in 2022.

DOCUMENTATION REVIEW

FDA reviewed nonconformance reports (NCRs) during the 2019, 2021, and 2022 inspections. FDA reviewed the Abbott facility's finished product testing, which showed one positive result for *Cronobacter* in Alimentum infant formula, according to the 2019 EIR. FDA noted in the EIR that a new NCR was created. FDA reviewed two additional NCRs for finished products that tested positive for *Cronobacter*, according to the 2021 EIR. One of the NCRs was initiated on September 25, 2019, 1 day after FDA concluded the 2019 inspection field work. Because the NCR was not initiated until the day after the 2019 inspection, FDA did not become aware of the positive *Cronobacter* result until the 2021 inspection, approximately 2 years after the 2019

inspection concluded. FDA requested NCRs for pathogen positive products from May 2020 to December 2021, according to the 2022 EIR. The EIR indicates that FDA received and reviewed the two NCRs during the 2021 inspection.

In addition, FDA reviewed documentation related to product destruction during the Abbott facility inspections. During the 2019 and 2021 inspections, FDA identified three batches of Abbott products that previously tested positive for *Cronobacter*. For each batch of product that tested positive for *Cronobacter*, FDA determined that the Abbott facility completed a documented review related to the positive *Cronobacter* test result, which included a disposition decision that the batches of product would be rejected and then destroyed.

For example, during the 2021 inspection, FDA obtained and reviewed an Abbott NCR that noted product that tested positive for *Cronobacter* in June 2020. The 2021 EIR stated that for an NCR, Abbott conducted a thorough investigation, yet the root cause was not determined. The EIR, however, did note sanitation, structural, personnel, and recordkeeping deficiencies. According to the Abbott NCR, corrective actions were implemented, and the affected batch was destroyed. Because FDA documented in the EIR that it identified product that tested positive for *Cronobacter* (document of product that fails to meet a specification/positive test results) and that the affected batch was rejected (material disposition decision) and then destroyed, FDA met its inspection documentation requirements.

During the 2022 inspection, FDA requested additional information related to the batch of product that tested positive for *Cronobacter* in June 2020. FDA officials stated that FDA requested this information because of the scope and findings cited in the 2022 inspection and to ensure that FDA obtained a "complete record." Of the 22,459 cases of product that Abbott was to destroy:

- FDA provided certification of destruction/reuse for 20,736 cases. According to FDA, the product was reused as animal (livestock) feed.

- FDA could not provide a certification of destruction/reuse for the remaining 1,723 cases. FDA stated that this product was incinerated, and that Abbott stated that its third-party vendor does not maintain incineration records.

FOOD SAFETY PLAN

FDA reviewed certain information in Abbott's food safety plan during the 2019, 2021, and 2022 inspections. FDA stated that the focus of the 2019, 2021, and 2022 inspections at Abbott was not to review and assess preventive controls (food safety plans) under 21 CFR part 117. However, FDA stated that it did review elements of Abbott's food safety plan during those inspections. During the 2019 inspection, FDA indicated that it reviewed and documented one of the seven food safety plan elements related to Abbott's written recall plan. During the 2021 inspection, FDA indicated that it reviewed and documented two of the seven food safety plan elements related to Abbott's written recall plan and its supply chain program. During the 2022

inspection, FDA indicated that it reviewed all seven food safety plan elements and documented its review of five of them.

FDA FOLLOWUP OF ABBOTT FACILITY INSPECTIONS

From September 16, 2019, to September 24, 2019, FDA conducted a surveillance inspection at the Abbott facility. FDA identified one inspectional observation and classified the inspection as "Voluntary Action Indicated" (VAI). According to the EIR, Abbott did not test a representative sample of a powdered infant formula at the final product stage and before distribution to ensure that the production aggregate met the required microbiological quality standards. FDA conducted followup with Abbott regarding the 2019 VAI-classified inspectional observations after the inspection concluded. Specifically:

- On September 24, 2019 (at the end of the 2019 inspection), FDA provided Abbott with an FDA Form 483 that listed one inspectional observation that Abbott did not test a representative sample of a production aggregate of a powdered infant formula at the final product stage and before distribution to ensure that the production aggregate met the required microbiological quality standards.

- On October 9, 2019, and November 1, 2019, FDA and Abbott met to discuss FDA's inspectional observation. During the November 1, 2019, meeting, Abbott verbally agreed to change its *Salmonella* testing procedures to sample 60 containers (as required by FDA regulations at 21 CFR §§ 106.55(c) and (e)).

- On November 8, 2019, Abbott emailed FDA a status update in which it agreed in writing to make the procedural change discussed in the November 1, 2019, meeting, and Abbott also provided revised sampling procedures.

- On January 15, 2020, Abbott provided another status update stating that it had implemented its new testing procedures as of December 18, 2019.

- On April 10, 2020, Abbott provided a third status update stating that it audited its sites to verify documentation and practices to confirm that 60 containers were being collected from each production aggregate and that 1 sample from each of the 60 containers was being tested for *Salmonella*.

- From September 20, 2021, through September 24, 2021, during the 2021 Abbott facility inspection, FDA verified that Abbott implemented corrective action related to the observation. Although Abbott implemented corrective action to come into compliance with FDA sampling policies, FDA could strengthen its finished product sampling requirements. During a March 2023 congressional hearing, a former FDA official stated, "[FDA's] rule currently says infant formula must be tested at an n=30 sampling plan. That means that 30 samples are taken, 10 grams of sample per each, 300 grams are

tested for *Cronobacter sakazakii*. Some of these manufacturing runs can be huge, 50[,000], 60,000 pounds. 300 grams is insignificant and the probability of them finding contamination is virtually zero."[71]

From September 20, 2021, to September 24, 2021, FDA conducted a surveillance inspection at the Abbott facility. FDA identified five inspectional observations and classified the inspection as VAI. According to the EIR: (1) Abbott did not maintain the facility in a clean and sanitary condition; (2) Abbott did not install the appropriate filters on its product filling machine; (3) personnel working directly with infant formula, its raw materials, packaging, or equipment or utensil contact surfaces did not wash hands thoroughly in a handwashing facility at a suitable temperature after their hands may have become soiled or contaminated; (4) certain system components were not calibrated; and (5) Abbott did not monitor certain equipment temperature at the appropriate frequency.

FDA conducted followup with Abbott regarding the 2021 VAI-classified inspectional observations after the inspection concluded. Specifically, on September 24, 2021, FDA provided Abbott management with an FDA Form 483 that listed five observations. On October 15, 2021, January 31, 2022, and April 30, 2022, Abbott provided FDA with status updates as to the progress it had taken in correcting the cited observations. During the 2022 inspection, FDA noted that four of the five 2021 inspectional observations were corrected. For the one 2021 inspectional observation that FDA stated was not corrected, FDA noted that Abbott had made progress, but there were a "few finishing touches to be completed."

From January 31, 2022, to March 18, 2022, FDA conducted a for-cause inspection at the Abbott facility. FDA identified four inspectional observations and classified the inspection as "Official Action Indicated." According to the EIR: (1) Abbott did not establish a system of process controls covering all stages of processing that was designed to ensure that infant formula does not become adulterated due to the presence of microorganisms in the formula or in the processing environment; (2) Abbott did not ensure that all surfaces that contacted infant formula were maintained to protect infant formula from being contaminated by any source; (3) Abbott's complaint investigation file did not include the determination as to whether a hazard to health exists and the basis for that determination; and (4) personnel working directly with infant formula, its raw materials, packaging, or equipment or utensil contact surfaces did not wear necessary protective apparel. FDA conducted followup on the 2022 inspectional observations through its monitoring under the consent decree. (See Appendix F.)

[71] United States House Committee on Oversight and Accountability, "FDA Oversight Part I: The Infant Formula Shortage" (timestamp 56:56), Mar. 28, 2003. Available online at https://oversight.house.gov/hearing/fda-oversight-part-i-the-infant-formula-shortage. Accessed on May 20, 2024.

FDA'S COMMUNICATION WITH KEY STAKEHOLDERS

FDA communicated its infant formula supply chain concerns to key stakeholders 1 day prior to the Abbott facility recall. According to FDA officials, FDA submitted a report on February 16, 2022, to U.S. Government partners, including White House contacts, on the potential voluntary recall and supply chain impacts given the significant market share held by Abbott Nutrition and the Sturgis facility being a critical producer of specialty metabolic and amino acid formulas. FDA stated that on February 23, 2022, it held a call with HHS and the U.S. Department of Agriculture (USDA) on infant formula activity and supply chain concerns.

FDA'S SUPPLY CHAIN AUTHORITY

FDA stated that, during our audit period, it did not have statutory authority or policies and procedures related to monitoring infant formula supply chains. Further, in its FY 2022 *Justification of Estimates for Appropriations Committees*, FDA sought legislative authority to require any manufacturer of infant formula to provide shortage notifications at a reasonable time and manner during a declared public health emergency.[72] In its FY 2023 *Justification of Estimates for Appropriations Committees*, FDA sought legislative authority to require manufacturers to notify FDA of anticipated significant interruptions in the supply of infant formula.[73]

On December 29, 2022, the Consolidated Appropriations Act of 2023 (the Act) was signed into law. Section 424 of the Act states that a manufacturer of a critical food, including infant formula, must notify FDA of a permanent discontinuance in the manufacture or an interruption of the manufacture of such food that is likely to lead to a meaningful disruption in the supply of such food in the United States, along with the reasons for such discontinuance or interruption, as soon as practicable, but not later than 5 business days after such discontinuance or such interruption. Prior to enactment of the Act, infant formula manufactures were not required to report meaningful disruptions in the supply of infant formula, which prevented FDA from having access to necessary information to monitor the supply chain of infant formula.

FDA'S ACTIONS TO ADDRESS THE INFANT FORMULA SHORTAGE BETWEEN SEPTEMBER 20, 2021, AND FEBRUARY 17, 2022

Although FDA was not statutorily mandated to monitor supply chains and lacked the authority to compel infant formula manufacturers to provide it with production data, FDA took action to address the potential shortage of infant formula leading up to the Abbott recall. According to FDA officials, FDA had an internal meeting on February 10, 2022, to discuss its response to the environmental test results from the Abbott facility. FDA officials stated that it notified USDA of

[72] FDA, *Justification of Estimates for Appropriations Committees*, 2022. Available online at https://www.fda.gov/media/149616/download. Accessed on May 20, 2024.

[73] FDA, *Justification of Estimates for Appropriations Committees*, 2023. Available online at https://www.fda.gov/media/157192/download. Accessed on May 20, 2024.

the situation on February 11, 2022.[74] FDA held another internal meeting on February 14, 2022, to discuss food safety, regulatory, and supply chain issues. On February 16, 2022, FDA sent a memo notifying relevant Government agencies.

[74] USDA administers the WIC program that provides grants to States to support distribution of supplemental foods including infant formula.

APPENDIX J: FDA COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

DATE: April 8, 2024

TO: Juliet T. Hodgkins, Principal Deputy Inspector General

FROM: Director, Public Health Strategy and Analysis

SUBJECT: FDA's General Comments to OIG's Draft Report Titled "The Food and Drug Administration's Inspection and Recall Process Should Be Improved to Ensure the Safety of the Infant Formula Supply" (A-01-22-01502)

Enclosed are the Food and Drug Administration's general comments to the Office of Inspector General's OIG Draft Report, "The Food and Drug Administration's Inspection and Recall Process Should Be Improved to Ensure the Safety of the Infant Formula Supply" (A-01-22-01502).

We appreciate the opportunity to review and comment on this draft report prior to publication.

Lisa B. Rovin -S
Digitally signed by Lisa B. Rovin -S
Date: 2024.04.08 15:40:02 -04'00'

Lisa Rovin, J.D.
Senior Advisor, Office of Economics and Analysis

Attachment

FDA's General Comments to OIG's Draft Report Titled, *The Food and Drug Administration's Inspection and Recall Process Should Be Improved to Ensure the Safety of the Infant Formula Supply*

The Food and Drug Administration appreciates the opportunity to review and comment on this draft report.

FDA takes seriously its duty to ensure the safety of the infant formula supply, with effective policies and procedures for preventing and timely responding to foodborne illnesses and food contamination events. We concur with OIG's recommendations and findings that FDA:

> "(1) 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; and
> (2) did not have the authority to require individuals and manufacturers to provide information that may have helped FDA to identify and respond to risks to the infant formula supply."

We are committed to implementing the OIG's recommendations for strengthening our program. As described below, FDA has begun several steps to improve policies and procedures for complaints, recalls, and infant formula inspections based on an internal, after-action evaluation of the Agency's infant formula response that was completed in September 2022. We also continue to pursue additional authority as OIG recommends.

FDA strongly agrees that adequate policies, procedures, and authorities are needed, and delays due to poor procedures are unacceptable and must be corrected. However, the report contains some statements that do not align with the available evidence. Specifically, the report presents findings and conclusions (pp. 8, 10, 18, and 21) that at least four reported illnesses, including two deaths, may have been preventable. These statements are predicated on a possible causal link between the Abbott facility and the reported cases, which was not substantiated by evidence from the investigation (described in Appendix E and footnote 35).

Laboratory analysis performed by Whole Genome Sequencing (WGS) of available patient samples for two reported cases did not find a genetic match to the strains of *Cronobacter* found in the Abbott facility, or to any other clinical isolates in the National Center for Biotechnology Informatics database.[1] Furthermore, the WGS showed that bacteria from these patient samples were not closely related to one another.[2] Lacking evidence of causation, FDA is not aware of other sufficient or appropriate evidence to support postulation. At a minimum, we believe that these findings and conclusions about illness prevention are incomplete and potentially misleading unless revised to clarify that evidence from the investigation does not substantiate a causal link between the Abbott facility and the reported cases. We also are providing technical edits based on this evidence from FDA's investigation.

[1] https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-infections-powdered-infant-formula-february-2022.
[2] https://www.cdc.gov/cronobacter/outbreaks/infant-formula.html.

Recommendation 1

FDA should prioritize maintaining the NCCC's continuity of operations by cross-training staff on whistleblower policies and procedures and NCCC duties, including monitoring the Occupational Safety and Health Administration whistleblower email inbox.

FDA Response

FDA concurs with OIG's recommendation.

In August 2021, FDA backfilled the National Consumer Complaint Coordinator (NCCC) position in FDA's Office of Security and Emergency Management (OSEM), Office of Emergency Management (OEM), Office of Emergency Operations (OEO). The NCCC keeps informed of activities and issues associated with complaints the Agency receives and serves as an authoritative source of information in this field. In June 2022, OEM approved internal, whistleblower complaint work instructions that apply to the NCCC, which is responsible for the receipt, review, and disposition of external whistleblower complaints about FDA-regulated industry. Additionally, this work instruction obligates OEO Emergency Coordinators to provide back-up to the NCCC, when needed. In August 2022, OEO approved NCCC work instructions that apply to all OEO staff responsible for the receipt, review, and disposition of external complaints about FDA-regulated products and industry. The NCCC has provided training on the Work Instructions to OEO staff members, and the OEO staff members currently assist in monitoring the OSHA Whistleblower Complaint e-mail box and FDA Emergency Operations e-mail box for whistleblower complaints and follow the work instructions. In June 2023, the NCCC co-hosted an FDA and OSHA-Whistleblower Protection Programs (WPP) annual meeting to discuss Agency points of contact, information sharing, and training opportunities. In August 2023, the NCCC co-hosted an OSHA whistleblower complaints training session for OEO staff, Office of Regulatory Affairs (ORA) Consumer Complaint Coordinators (CCCs), and CCC Supervisors. Currently, OEM management and the NCCC attend FDA-wide whistleblower complaint work group meetings hosted by FDA Office of the Chief Counsel (OCC) to keep apprised of upcoming policy changes and plans to implement new policies related to the Agency's handling of complaints, including whistleblower complaints.

Recommendation 2

FDA should develop and implement policies and procedures requiring periodic reporting (e.g., monthly reporting) to senior leadership on the status of open whistleblower complaints.

FDA Response

FDA concurs with OIG's recommendation.

FDA has instituted multiple system improvements within CFSAN and ORA to strengthen the escalation and periodic reporting process for complaints, including whistleblower complaints.

For whistleblower complaints, CFSAN's Office of Compliance (CFSAN-OC) has developed a process to track, evaluate, follow-up, and notify compliance leadership of regulatory misconduct complaints, which includes whistleblower complaints. CFSAN has established an email box where FDA personnel send all whistleblower complaints for CFSAN-regulated products, including infant

formula. Once CFSAN receives the complaint, OC triages the complaint and logs the complaint using a newly developed application. After OC logs the complaint, the system will automatically send the complaint for assignment and follow-up with subject matter experts and ORA personnel, as appropriate. Because all whistleblower complaints are designated as priority complaints, the application also notifies CFSAN compliance leadership of them. CFSAN developed an SOP to formalize this process.

For all infant formula-related events, including whistleblower complaints, CFSAN has developed a leadership notification memorandum, which lays out which infant formula-related events will be elevated to the highest levels of FDA leadership, who in FDA leadership will receive the notifications, which office will be responsible for sending the notifications, and generally what information will be contained within a notification. The leadership notification memorandum covers four general categories of infant formula-related events: (1) adverse event reports/consumer complaints, (2) regulatory misconduct complaints (which includes whistleblower complaints), (3) infant formula-related compliance and enforcement actions, and (4) powdered infant formula *Cronobacter* spp. or *Salmonella* product positive notifications. Additionally, the memorandum clearly defines when leadership can expect follow-up notifications, including when there is new information of significance or significant upcoming events or actions.

For complaints more generally, ORA has revised its internal complaint procedure to better define when certain complaints need to be escalated to senior officials. See https://www.fda.gov/food/conversations-experts-food-topics/fda-works-protect-consumers-foodborne-illness-and-other-adverse-events. This change involves rapid escalation of reports of life-threatening injury/illness or death to the highest levels of the Agency and specifically addresses triggers for escalation of reports of any hospitalization or death involving an infant. Specifically, on June 2, 2023, ORA released (TN-005635) SOP-000099 Rev.05 (ORA Hot Items Reporting) with improvements to the process of escalating reports to the Associate Commissioner of Regulatory Affairs (ACRA). The SOP includes an Appendix A listing items (including whistleblower complaint handling) that ORA reports on a daily or weekly basis to the ACRA and other senior leaders in ORA and the Centers. Additionally, SOP-000544 rev 5 (Consumer Complaint Procedure) is slated to be released in April 2024 and will address escalation of complaints, including whistleblower complaints, to both Centers and ORA Program Offices and will include clearer definitions on what should be escalated, how to escalate, and how to regularly update senior leadership on open issues (including, but not limited to, whistleblower complaints). ORA has also established and released an internal ORA Consumer Complaint Dashboard to better track complaints received, accomplished, and time frames for established milestones.

Recommendation 3

FDA should implement policies and procedures that facilitate reporting consumer complaints in real time to investigators onsite when an active inspection is occurring at the facility identified in the complaint.

FDA Response

FDA concurs with OIG's recommendation.

The agency understands the finding and agrees there are opportunities to improve but would note that it is often not possible to associate a complaint with a firm location on the date the complaint is received; some initial follow-up and investigation is typically needed to gather sufficient information to make that connection. FDA has established processes requiring personnel who receive complaint information to distribute it more widely and incorporate it into decisions to support regulatory compliance and public health. FDA is also working on longer term IT improvements that will make this currently manual process a systematic one. For example, complaint information, compiled from multiple data sources, is manually being shared across FDA to help inspection preparation. System enhancements to ORA Applications will allow complaints with complete information received before the close of an inspection to be accessible to an investigator conducting the inspection to ensure coverage of the complaint. In addition, ORA and CFSAN have created elevation distribution lists, standard operating procedures, and mechanisms for emerging public health issues to be shared across FDA Centers.

Recommendation 4

FDA should strengthen the QFC process to identify data entry inaccuracies.

FDA Response

FDA concurs with OIG's recommendation.

The Consumer Complaint QFC Form is being revised to identify timeframes. The Consumer Complaint Procedure (SOP-000544 rev 5) will address methods for planned follow-up assignments to be linked to complaints and to establish timeframes for initial dispositions. Revisions will include instructions and examples to help increase the accuracy of identifying the initial disposition status.

Additional ORA complaint system enhancements either have been released, or are scheduled to be released, in 2024 to address inaccuracies in multiple areas, including, but not limited to, recording complaint numbers appropriately, documenting complaint coverage in assignments, and ensuring entry of timely and accurate follow-up dispositions.

Recommendation 5

FDA should formalize written policies and procedures that either:

- require that the CAERS coordinator forward all reports that originate in CAERS to the NCCC or

- identify specific factors that the CAERS coordinator must consider when determining if adverse event reports should be forwarded to the NCCC and include specific examples of types of adverse event reports that do not need to be forwarded to the NCCC.

FDA Response

FDA concurs with OIG's recommendation. However, as noted in our technical comments, we suggest rewording the first bullet to read "require that the CAERS coordinator forward all reports that did not originate in FACTS to the NCCC".

In May 2021, Standard operating procedures (SOPs) were modified and adopted to improve operations to share all adverse event and product problem reports with the NCCC. The CAERS coordinator shares a weekly report with the NCCC of all CAERS reports that did not originate in FACTS.

Recommendation 6

FDA should 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 mission-critical inspections are conducted in a timely manner.

FDA Response

FDA concurs with OIG's recommendation.

FDA prioritizes inspections based on risk to public health. Those considered to be critical to FDA's public health mission receive the highest priority and are conducted timely, even under adverse conditions such as the COVID-19 pandemic. FDA established criteria that were applied on a case-by-case basis to identify mission-critical oversight work, which continued to be conducted during the pandemic. FDA will use these criteria as a starting point for developing policies and procedures that govern how and when mission-critical inspections need to be conducted and timely completed during public health emergencies.

Recommendation 7

FDA should design and implement policies and procedures specific to the use of its FDA-required infant formula recall authority.

FDA Response

FDA concurs with OIG's recommendation.

Section 412(e)(1)(B) of the FD&C Act provides FDA with mandatory recall authority for infant formula when an infant formula is adulterated or misbranded and presents a risk to human health. Section 412(f) of the FD&C Act sets forth the requirements of such a mandatory recall, and our implementing regulations are found in 21 CFR 107.

Our statutory authority in Section 412(f) and our implementing regulations at 21 CFR 107 set forth the scope and effect of such mandatory infant formula recalls, describe the elements of such a recall (including posting written notification at the point of sale at retail establishments); notification requirements the recalling firm must provide to FDA (including bi-weekly ongoing

status reports until the recall is terminated); criteria for terminating the recall; procedures for how to revise the scope of an infant formula recall; details on the record retention that is required; and a reference to comply with our recall procedures set forth in Part 7 of our regulations to the extent that such procedures "may be useful to a recalling firm in determining how to comply with these regulations." For example, FDA's guidance entitled Initiation of Voluntary Recalls under 21 CFR Part 7, Subpart C, may be useful to assist an infant formula manufacturer with initiating a recall promptly.

FDA has not required a recall of infant formula under 21 CFR 107.200 in the past 30 years. Had FDA needed to conduct a mandatory infant formula recall in 2022, FDA determined that it would have followed its recall procedures set forth in section 412 of the FD&C Act and its recall regulations at Part 107 and Part 7. In addition, FDA determined that it would have generally followed the regulatory hearing process outlined in Part 16 of its regulations, as well as Section 423 of the FD&C Act (mandatory recall authority for all other foods that are not infant formula) for conducting a hearing to satisfy the due process requirements of the Fifth Amendment.

The Regulatory Procedures Manual (RPM) chapter and section on recalls (Chapter 7), Attachment J, Mandatory Recall Authority for Foods, provides procedures, a process flow chart, and steps for conducting the hearing. Attachment F, Recalls of Infant Formula, provides a timeframe (5 calendar days) for FDA to evaluate, prepare a memorandum, and approve an infant formula manufacturer's recall notification. Attachment F also states that infant formula recalls are to be handled under the same procedures as other recalls with two additions dealing with the manufacturer's written notice of the recall and the manufacturer's report to FDA. FDA will consider whether additional procedures are needed to effectively use its FDA-required infant formula recall authority.

CFSAN-OC's recalls team developed an internal resource document for mandatory recalls, including infant formula, during FY 2023. This document is nearing completion and summarizes the legal thresholds, circumstances to consider initiating mandatory recall, sample mandatory recall letters, and information about the expert statements necessary to support it. As part of this internal resource, we are also including information regarding infant formula recalls under Section 412 and how they differ from the mandatory recall authority in Section 423 for other foods. As part of the document development, the recalls team also conducted an internal training for the CFSAN recalls team and compiled a separate resource folder to assist in streamlining efforts associated with mandatory recalls. As part of this process, FDA will consider whether these internal resources are appropriate for consideration in the RPM or associated attachments.

Although there are differences between infant formula recalls (FDA's general recalls procedures under 21 CFR Part 7 and 21 CFR Part 107), FDA will consider whether procedures specific to infant formula recalls will benefit public health or if modifications to existing resources such as the RPM, coupled with other updates, are sufficient.

Recommendation 8

FDA should amend the language on the CAERS adverse event report form to emphasize the importance of including the lot number to encourage the public to report this information.

FDA Response

FDA concurs with OIG's recommendation.

Although FDA is unable to legally require the public to provide product lot numbers when reporting illnesses and other issues, reporting form modifications have been created to ease and encourage voluntary reporting of product lot and other sparsely received complaint and adverse event information from consumers and healthcare providers. Comprehensive literature reviews, analysis of existing data, cognitive interviews, and usability studies were conducted to provide best practical plain language and other improvements for the public to enhance collection of data on new FDA reporting forms. In addition, to increase awareness of how the public can report issues to FDA, outreach materials such as stakeholder toolkits, social media posts, GIFs, and public health success stories are being developed. Lastly, FDA has created a master product data set and mechanism for mobile and desktop reporters to auto-populate further product information when consumers submit incomplete product details on FDA reporting forms, which will ultimately capture better product information from the public. Currently, FDA is in the process of clearing a new reporting form for CAERS submissions, which emphasizes the need for clear product information, including lot codes and product photos, to be rolled out to consumers soon.

Recommendation 9

FDA should continue to seek legislative authority to require infant formula manufacturers to notify and provide the bacterial isolate to FDA every time a product sample is found to be positive for *Cronobacter* or *Salmonella*, even if the affected lots have not been distributed, and update its existing databases with the information received.

FDA Response

FDA concurs with OIG's recommendation.

FDA has taken numerous steps, many of which are outlined in our Strategy to Help Prevent Cronobacter sakazakii Illnesses Associated with Consumption of Powdered Infant Formula, to encourage the reporting of positive *Cronobacter* findings from a variety of sources, including infant formula manufacturers. In March 2023, as part of the prevention strategy work, the FDA sent a letter to the powdered infant formula industry to share current safety information and called on the industry to take prompt action to improve processes and programs for the protection of our most vulnerable population. This letter also contained a request to industry that they "voluntarily notify the Agency any time a product sample is found to be positive for *Cronobacter* spp. or *Salmonella*, even if the affected lot(s) have not been distributed."

In the fiscal year (FY) 2024 budget request that FDA submitted to Congress in March 2023, FDA formally requested the authority to require infant formula manufacturers to notify FDA of any product that tests positive for pathogen contamination, regardless of the disposition of that product. Although FDA's legislative proposal for mandatory reporting of product positives (for product under the manufacturer's control) did not appear in a budget request until FY 24, FDA had communicated to the Hill the need for this authority in June 2022, as part of a package of infant formula food safety and supply chain authorities prepared for the House Energy and Commerce Committee and Senate Health, Education, Labor, and Pensions bipartisan staffs for infant formula hearing follow-up. Since

this time, FDA has remained in contact with the Hill providing input and technical assistance as needed.

As a result of these actions, on August 29, 2023, Rep. Katie Porter (D-CA), the Ranking Member on the Oversight Subcommittee on Health Care and Financial Services, and Chairwoman Lisa McClain (R-MI) introduced a bipartisan bill that would help prevent another infant formula crisis. The Safeguarding Kids and Families from Critical Food Shortages Act would require formula manufacturers to report to the Food and Drug Administration (FDA) within 24 hours any time their infant formula gets contaminated by a pathogen. Also, on December 18, 2023, Rep. Emilia Sykes (OH-13), Frank Pallone, Jr. (NJ-06), Raja Krishnamoorthi (IL-08), and Tony Cárdenas (CA-29) introduced the Improving Newborns' Food and Nutrition Testing Safety (INFANTS) Act. Among other things, this legislation clarifies that infant formula manufacturers must notify FDA within 24 hours if they acquire knowledge that the infant formula they manufacture does not contain adequate nutrients or is otherwise adulterated or misbranded.

Finally, FDA, in collaboration with CDC, supported the Council of State and Territorial Epidemiologists (CSTE) position on elevating *Cronobacter* to a nationally notifiable disease in infants. With this support, the CSTE successfully passed this vote on June 29, 2023. *Cronobacter* notification took effect at the beginning of 2024, decisioned on a state-by-state basis. FDA continues supporting and working with states on these efforts. This additional source of clinical isolates, coupled with FDA's work to collect and sequence environmental and product samples, will increase available sequences in the NCBI database and help address scientific data gaps pertaining to *Cronobacter*.

OTHER MATTERS

BETTER DOCUMENTATION NEEDED FOR INITIATING INFANT FORMULA FOLLOWUP ACTIVITIES

FDA Response

Consumer complaint handling procedures are currently being revised to include additional definitions of relevant terms and to establish timeframes within the complaint process. Revisions will also define expectations related to regulatory follow-up, including investigations, inspections, and sample collections. We expect these definitions and enhancements to be adopted with the release of Consumer Complaint Procedure (SOP-000544 rev 5) slated for release in April 2024.

THE FDA INSPECTION SCHEDULES ARE TOO PREDICTABLE

FDA Response

FDA considers a variety of factors, including food safety signals and supply chain considerations, when scheduling infant formula inspections. FDA will inspect food facilities more frequently when food safety signals arise.

Routine domestic surveillance infant formula inspections are unannounced to minimize predictability and FDA now aims to ensure that inspections are not scheduled at the same time

each year. Foreign infant formula inspections continue to be preannounced to ensure traveler safety, the selection of personnel with appropriate expertise, and making certain that the foreign facility will be in operation at the time of the inspection. Entry requirements for some foreign countries may require engagement with the foreign facility prior to entry, obtaining necessary visa(s), or travel clearances.

Other changes that FDA has made to date are here: https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/status-update-fdas-infant-formula-response-activities.