U.S. FOOD & DRUG ADMINISTRATION

September 16, 2022

The Honorable Frank Pallone, Jr.
Chairman
Committee on Energy and Commerce
Washington DC, 20515-6115

Dear Chairman Pallone:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the May 25, 2022 hearing before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce entitled "Formula Safety and Supply: Protecting the Health of America's Babies." This letter is a response for the record to questions posed by the committee.

Sincerely,

Kimberlee R. Trzeciak -S
Digitally signed by Kimberlee R. Trzeciak -S
Date: 2022.09.16 19:25:03 -04'00'

Kimberlee Trzeciak
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Additional Questions for the Record

Subcommittee on Oversight and Investigations
Hearing on
"Formula Safety and Supply: Protecting the Health of America's Babies"
May 25, 2022

The Honorable Robert M. Califf, M.D., Commissioner, Food and Drug Administration

The Honorable Frank Pallone, Jr. (D-NJ)

1. **Commissioner Califf, you testified before the Subcommittee that once FDA received positive *Cronobacter* results from the samples taken from the Abbott Sturgis, Michigan facility, the Agency took action, including sending memos to relevant agencies signaling the supply chain risk. In addition, your testimony referenced memos developed by FDA describing the issues and concerns related to infant formula for the White House. Please provide these memos to the Committee.**

As noted in previous timelines that we have shared publicly, on February 16, 2022, the U.S. Food and Drug Administration (FDA), as a Co-Sector Risk Management Agency of the Food and Agriculture Sector, submitted a report to U.S. government (USG) partners on the potential recall and supply chain impacts given the significant market share held by Abbott Nutrition as well as the Sturgis facility being a critical producer of specialty metabolic and amino acid formulas. FDA began regular updates and coordination with our USG partners on the supply chain as noted in our timeline. We are committed to working with the Committee on these issues, and FDA staff will follow up with your staff to discuss next steps regarding the memoranda.

2. **FDA's written testimony states that on April 1, 2022, FDA transferred its response activity to an agency-wide Incident Management Group (IMG). Please provide:**
   a. **The names, offices, and titles of each member of the IMG.**

   The following table lists members of FDA's Infant Formula IMG and their functions:

Role	Name	Office/Center
Agency Incident Coordinator	**Frank Yiannas**	OFPR
Deputy Agency Incident Coordinator	**CAPT Joshua Simms**	OEM
CDC Liaison Officer	Susan Lance	CFSAN
USDA Liaison Officer	Claudine Kavanaugh	CFSAN
Legal	Carrie James	OCC
Legal	Peter Beckerman	OCC
Legal	Shannon Singleton	OCC
Legislative	Matthew Lockeed	OL
Public Information Officer	Dan Hetlage	OMA
Planning Section Chief	**LCDR Kimberly Garner**	OEM
Planning Section Deputy	Stelios Viazis	CORE
Situation Unit Leader	**Carole Dieterly**	OEM
Situation Unit Specialist	LT Morgan Lee	OEM
Documentation Unit Leader	**Vanessa Williams**	OEM
Documentation Unit	Heidi Debeck	ORA
Documentation Unit	CDR Monique Lester	OEM
Operations Section Chief	**Tanya Malais**	ORA
Operations Deputy	Stranjae Ivory	CORE
Supply Chain Chief – Pediatric Medical Expert	Joseph Toerner	CDER
Supply Chain Deputy	Caitlin Boon	OFPR
Supply Chain Disruption Mitigation Unit Leader	**CDR Hyun Son**	CDER
Supply Chain Disruption Mitigation Unit Deputy	Claudine Kavanaugh / Pat Hansen	CFSAN
Supply Chain Disruption Mitigation Unit Specialist	LeeAnne Jackson	CFSAN
Supply Chain Disruption Mitigation Unit Specialist	Andrea Lotze	CFSAN
Supply Chain Disruption Mitigation Unit Specialist	Carrie Assar	CFSAN
Supply Chain Disruption Mitigation Unit Specialist	Carol Stiller	CDER
Supply Chain Disruption Mitigation Unit Specialist	Melissa Ramos	OFPR
Supply Chain Disruption Mitigation Unit Specialist	Allison Scott	ORA
Supply Chain Disruption Mitigation Unit Specialist	Ashley Abraham	ORA
Data Analytics/GIS Leader	**Nathan Beck**	OEM
Data Analytics/GIS Deputy	Suzanne Roosen	OFPR
Data Analytics/GIS Specialist	Ahmed Askar	OEM
Data Analytics/GIS Specialist	Jose Vicente Ruiz	CDER
Data Analytics/GIS Specialist	Bohan Niu	OFPR

Data Analytics/GIS Specialist	Xin Liu	OFPR
Data Analytics/GIS Specialist	David Oryang	CFSAN
Data Analytics/GIS Specialist	Adam Friedlander	OFPR
Data Analytics/GIS Specialist	LCDR Silvia Wanis	CDER
Data Analytics/GIS Specialist – CDER Shortage Staff	CDR Hyun Son	CDER
Data Analytics/GIS Specialist	Yuhuan Chen	CFSAN
International Operations Unit Leader	**Russell Zablan**	OEM
International Operations Specialist	Teresa Fox	CFSAN
Consumer Complaints Unit Leader	**Sheila VanTwuyver**	OEM
Consumer Complaint Specialist	Stephanie Chastagner	ORA
Food Safety & Response Leader	**Ann Oxenham**	CFSAN
Food Safety & Response Deputy	Karl Klontz / Kathleen Gensheimer / Alvin Crosby	CFSAN
Food Safety & Response Specialist	Vinetta Howard-King	ORA
Food Safety & Response Specialist	Marjorie Davis	CFSAN
Food Safety & Response Specialist	CDR Catherine Beer	ORA
Food Safety & Response Specialist	Julia Manetas	ORA
Food Safety & Outbreak Response Specialist	Stuart Chirtel	CFSAN
Food Safety & Outbreak Response Specialist	Les Smoot	CFSAN
Food Safety & Outbreak Response Specialist	Jamie Pettengill	CFSAN
Logistics Section Chief	**LCDR Henry Allen**	OEM
ORA Specialist	**Catherine Beer**	ORA

Legend: CDER (Center for Drug Evaluation and Research); CFSAN (Center for Food Safety and Applied Nutrition); CORE (Coordinated Outbreak Response and Evaluation Network); OCC (Office of the Chief Counsel); OEM (Office of Emergency Management); OFPR (Office of Food Policy and Response); OL (Office of Legislation); OMA (Office of Media Affairs); ORA (Office of Regulatory Affairs).

b. How frequently the IMG meets and how long the Agency anticipates the IMG remaining in effect.

FDA's Infant Formula IMG's subgroups meet with various frequency, as follows:

- Daily (Monday through Friday):
  - IMG Data Analytics Team
- Three times per week:
  - IMG Supply Chain Disruption Mitigation Unit
- Twice per week:
  - IMG (full session)
  - IMG Food Safety and Response Unit
  - IMG Planning Section
- Once per week:
  - IMG Command and General Staff

- IMG Operations Section
- IMG Data Analytics and Geographic Information Systems (GIS) Team
- IMG Operations and Planning sections (joint meeting)
- FDA individual supply chain discussions with Abbott Nutrition, Meade Johnson Nutrition-Reckitt, Nestle-Gerber, Nutricia-Danone, and Perrigo
- FDA and the U.S. Department of Agriculture (USDA)

FDA anticipates the IMG remaining in effect until the current supply disruption resolves.

c. A description of how and whether the IMG's mandate and composition differs from any group(s) previously charged with overseeing the response to the shortage.

Beginning on February 14, 2022, an FDA intra-agency group, including experts and leadership from OFPR, CFSAN, and ORA, began discussions related to the infant formula supply chain in addition to ongoing food safety and regulatory issues related to the Abbott Nutrition response. It is important to recognize that while the medical product centers have dedicated staff for addressing shortages, FDA's Foods Program does not have these resources and is doing this work by reallocating staff and resources from other key activities.

On April 1, 2022, FDA transformed its response activities to an Agency-wide IMG to coordinate the Agency's response to the incident because of the impact on infant health and product supply and in accordance with the FDA Emergency Operations Plan. The Emergency Operations Plan provides that an IMG is typically established when an incident involves multiple FDA organizational components or involves (or is anticipated to involve) complex incident management/coordination. The IMG includes leadership and subject matter experts from across the Agency, including from the following components:

- Center for Drug Evaluation and Research
- Center for Food Safety and Applied Nutrition
- Coordinated Outbreak Response and Evaluation Network
- Office of the Chief Counsel
- Office of Emergency Management/Office of Emergency Operations
- Office of Food Policy and Response
- Office of Legislation
- Office of Media Affairs
- Office of Regulatory Affairs

The broader composition of the IMG leverages areas of expertise like medical product shortages and emergency operations. The IMG also provides more support to the original team to acquire and analyze data, sustain existing activities, and expand activities to address the ongoing supply chain challenges.

The Honorable Diana DeGette (D-CO)

1. On June 8, 2022, several outlets reported that the Department of Labor's (DOL) Occupational Safety and Health Administration (OSHA) shared a complaint with the

Food and Drug Administration (FDA) from an Abbott employee detailing various safety and sanitation concerns at Abbott's Sturgis, Michigan plant in February 2021.

a. Did the Agency receive such an OSHA complaint transmitted from DOL and if so, on what date?

FDA received the OSHA complaint electronically on February 19, 2021.

b. When did Director Mayne, Deputy Commissioner Yiannas, and you, Commissioner, respectively, each become aware of the complaint?

As of May 25, 2022, Dr. Califf, Dr. Mayne, and Deputy Commissioner Yiannas had not been alerted about the OSHA complaint.

c. Have any of FDA's inspections of the Abbott Sturgis facility incorporated an investigation of allegations specified in the February 2021 PSHA complaint? If so, please describe these further.

FDA's January 2022 inspection of Abbott Nutrition's Sturgis, Michigan, facility incorporated information from both the February 2021 OSHA complaint and the October 2021 confidential informant complaint and subsequent interview with that confidential informant in December 2021. A comparison of the two complaints proved them to be identical in the scope of their allegations.

2. I commend the Administration for Operation Fly Formula as it appears to be addressing many of the previously reported concerns related to delays in FDA approval to import formula into the United States. Outside of the current emergency operations, however, please provide further information regarding the 1) average number of applications FDA receives per year (over the past four to import formula from abroad, how FDA prioritizes these applications, the numbers of applications approved, denied, and in review (and the number of cans or cases of formulas represented in each application), and the average processing time for each application that has been reviewed or denied.

For clarification, FDA receives infant formula submissions, not "applications." FDA does not "approve" infant formula. All infant formulas sold in the United States, whether manufactured in the United States or imported, must meet the applicable requirements of section 412 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350a) and associated regulations in 21 CFR Parts 106 and 107. For new infant formulas, this includes the requirement for premarket registration and notification to FDA (see sections 412(c)&(d)(1) of the FD&C Act and 21 CFR 106.110, 106.120).

Premarket infant formula submissions include the following: (1) new infant formula submissions (21 CFR 106.120), (2) before first processing (BFP) infant formula submissions (21 CFR 106.140), and (3) export-only new infant formula submissions (21 CFR 106.120). A new infant formula submission is required for a new infant formula, which includes an existing infant

formula with a major change,[1] and must be submitted to FDA at least 90 days before introducing the infant formula into interstate commerce. A BFP infant formula submission is required when there is a non-major change to an existing infant formula, and it must be submitted before the first processing of such infant formula. An export-only new infant formula submission is required for a new infant formula that is manufactured in the United States strictly for export to a foreign country (i.e., no domestic distribution).

The review of infant formula submissions is generally first-in, first-worked-on, with new infant formula submissions typically being the highest priority. However, we take into account public health and safety considerations. For example, we prioritized submissions related to sunflower oil shortages associated with the war in Ukraine, alternate amino acid mixes for specialty formulas in short supply, and packaging components that have been difficult to obtain due to the COVID-19 pandemic to help ensure a safe and nutritionally adequate supply of infant formula.

The number of infant formula submissions that FDA receives each fiscal year (FY) can vary greatly. Below are tables that provide the number of infant formula submissions received the last four fiscal years as well as in FY 2022 up to May 25, 2022. The first table includes the total number of submissions, and the other tables provide a breakdown of submissions that were completed or under review, not accepted for review by FDA (incomplete submissions),or withdrawn by the submitter.

	TOTAL SUBMISSIONS RECEIVED			
	New/Major Change	BFP	Export	Total
FY 2019	40	49	17	106
FY 2020	49	41	7	97
FY 2021	56	73	9	138
FY 2022 (as of 5/25/2022)	36	62	9	107

[1] Per 21 CFR 106.3, *major change* in an infant formula means any new formulation, or any change of ingredients or processes where experience or theory would predict a possible significant adverse impact on levels of nutrients or bioavailability of nutrients, or any change that causes an infant formula to differ fundamentally in processing or in composition from any previous formulation produced by the manufacturer. *Examples* of infant formulas deemed to differ fundamentally in processing or in composition include the following:

(1) Any infant formula produced by a manufacturer who is entering the U.S. market;
(2) Any infant formula powder processed and distributed by a manufacturer who previously only produced liquids (or vice versa);
(3) Any infant formula having a significant revision, addition, or substitution of a macronutrient (i.e., protein, fat, or carbohydrate), with which the manufacturer has not had previous experience;
(4) Any infant formula manufactured on a new processing line or in a new plant;
(5) Any infant formula manufactured containing a new constituent not listed in section 412(i) of the FD&C Act (21 U.S.C. 350a(i)), such as taurine or L-carnitine;
(6) Any infant formula processed by a manufacturer on new equipment that utilizes a new technology or principle (e.g., from terminal sterilization to aseptic processing); or
(7) An infant formula for which there has been a fundamental change in the type of packaging used (e.g., changing from metal cans to plastic pouches).

	COMPLETED REVIEW			
	New/Major Change	BFP	Export	Total
FY 2019	19	44	15	78
FY 2020	38	33	7	78
FY 2021*	41	65	9	115
FY 2022* (as of 5/25/22)	29	56	5	90

* Indicates some portion of reviews submitted during the fiscal year may still be under review as of 05/25/22.

	NOT ACCEPTED FOR REVIEW (INCOMPLETE)			
	New/Major Change	BFP	Export	Total
FY 2019	5	3	1	9
FY 2020	9	0	0	9
FY 2021	8	6	0	14
FY 2022 (as of 5/25/22)	4	4	0	8

	WITHDRAWN			
	New/Major Change	BFP	Export	Total
FY 2019	16	2	1	19
FY 2020	2	8	0	10
FY 2021	7	2	0	9
FY 2022 (as of 5/25/22)	3	2	4	9

Currently, we do not collect information on the average review time for an infant formula submission, as the range of time for submissions can vary substantially depending on the type of submission, receipt of a substantive amendment (which occurs in most cases with a new infant formula submission), the firm's response time to FDA questions, and other events that prevent a new firm or product from initially submitting a complete and accurate initial submission.

The Honorable H. Morgan Griffith (R-VA)

1. **The U.S. Food and Drug Administration's (FDA) testimony notes that given the two case complaints—in September and December—and the potential severity of *Cronobacter* infections, along with the complaint from a former employee—that FDA received in October—FDA initiated inspectional planning for a for-cause inspection at the Sturgis facility on December 6, 2021, with an anticipated inspection date in early January 2022. However, the timeline in the appendix to FDA's written testimony states that on October 21, 2021, FDA received the whistleblower complaint, the complaint was**

reviewed by multiple FDA staff, and FDA began planning for an inspection at the Sturgis Facility then. Did FDA start planning for an inspection of Abbott's Sturgis, Michigan plant in October 2021 or December 2021?

Addressing the situation at Abbott Nutrition's Sturgis, Michigan, facility began in October 2021 and continued through December 2021. FDA received a complaint from a confidential informant on October 21, 2021, and spent six weeks investigating the complaint's allegations and planning an inspection of Abbott Nutrition's Sturgis, Michigan, facility. Specifically, we immediately acknowledged receipt of the complaint on October 2021, and food safety components of the Agency began evaluating the complaint, discussing the parameters of the case, and planning an inspection of Abbott Nutrition's Sturgis facility in that same time frame. As part of this planning, we interviewed the confidential informant as soon as the confidential informant and attorney were available.

a. If there were two different types of planning that occurred in October and in December, please explain the difference between the planning activities in October and those in December.

Planning was ongoing as FDA received and investigated complaints. We discussed the potential nature of the confidential informant's case and developed interview questions for the confidential informant to add specificity to the allegations made in the complaint. FDA requested an interview with the confidential informant in early December, but due to the availability of the confidential informant and attorney, the interview took place on December 22, 2021. We required information from this interview to finalize our inspection planning.

b. Why did it take FDA so long from the moment it decided to initiate an inspection to actually inspect the Sturgis facility?

FDA fully evaluated and considered the complaints and information as we received them, which ultimately lead to a decision to inspect Abbott Nutrition's Sturgis, Michigan. We received a consumer complaint of *Cronobacter* illness from the Minnesota Department of Health on September 20, 2021. We immediately notified Abbott Nutrition of the complaint and collected product samples for analysis. FDA's Southeast Food and Feed Laboratory reported no *Cronobacter* findings in the samples collected from the first complaint.

FDA then received a complaint from a confidential informant on October 21, 2021. While we evaluated and investigated this complaint, we began planning for an inspection of the Sturgis facility, which involved considering the nature of the allegations and developing a strategy for follow-up. We attempted to schedule an interview with the confidential informant in early December, but we were not able to meet with the informant until December 22, 2021. Further, we had nearly completed planning for a for-cause inspection incorporating the October 2021 confidential informant complaint when we received the December *Cronobacter* complaint. Upon receipt of the December complaint, we incorporated it into our planning of the for-cause inspection at the Sturgis facility.

On December 20, 2021, FDA notified Abbott Nutrition that it intended to conduct an inspection on January 3, 2022, but Abbott Nutrition asked for a delay, citing an ongoing COVID-19 outbreak in the facility. FDA agreed to delay the inspection, and on January 11, 2022, during this delay, FDA received a third illness complaint associated with Abbott Nutrition's infant formula. This complaint also reported *Cronobacter* illness. Infant formula samples were collected that tested negative for the presence of *Cronobacter*. On January 31, 2022, despite a worsening COVID-19 outbreak at the facility, FDA initiated the inspection.

2. **On May 16, FDA issued guidance to manufacturers of infant formula to announce the agency's intention to temporarily exercise enforcement discretion, on a case-by-case basis, for certain requirements that apply to infant formula. The guidance is related to both the importation into the U.S. of infant formula produced in other countries and infant formula that is produced domestically. The FDA noted that it will use this information to consider on a case-by-case basis whether to exercise enforcement discretion. One example listed on FDA's website is that "for an infant formula with a label that does not list the nutrients in the order required, the FDA may determine that enforcement discretion is appropriate."**

   a. **Assuming all the required nutrients are in the infant formula product and the product is otherwise safe, why does the order in which the nutrients are listed on the label matter?**

Requirements for infant formula exist at section 412 of the FD&C Act and our regulations at 21 CFR parts 106 and 107. Section 412(i)(1) of the FD&C Act and 21 CFR 107.10 establish labeling requirements for infant formula, including the order of nutrients, specified units, and tabular format. A consistent format for labeling, including specific listing of nutrients, permits consumers to compare products easily to make informed choices. However, in our guidance document announcing our temporary exercise of enforcement discretion, we note that we will evaluate infant formula on a case-by-case basis.[2] If an infant formula with a label does not list the nutrients required in order, but complies with all other FDA requirements, FDA is likely to find that enforcement discretion is appropriate.

3. **In response to a question I asked during the hearing about how many enforcement discretion requests were pending with the FDA, Dr. Mayne stated that as of the evening of May 24, 2021, FDA had "26 different people who have applied through our portal," and "one of those was approved." For each of the 26 applications that FDA received at the time of the hearing, please specify when FDA received each application.**

We would like to clarify that the language used by Dr. Mayne as quoted in the question is imprecise. FDA does not "approve" infant formulas generally or "approve" requests for

[2] U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, "Infant Formula Enforcement Discretion Policy: Guidance for Industry," May 2022, available at https://www.fda.gov/media/158476/download.

enforcement discretion. We also disagree with the characterization of the requests for enforcement discretion as "applications." Such terminology is generally associated with applications for product approval.

FDA published its enforcement discretion guidance on May 16, 2022.[3] We received 26 requests for enforcement discretion in the ten days between May 16 and May 25, 2022. During this span, we sent a letter affirming our intent to exercise enforcement discretion for one – for an estimated 2 million cans of infant formula, or 58.1 million estimated full-size 8-ounce bottles – by United Kingdom producer Kendal Nutricare Ltd., and we have continued to evaluate the remaining requests for their suitability for enforcement discretion. We maintain an updated list of manufacturers receiving enforcement discretion on our website.[4]

a. Has FDA approved additional enforcement discretions since the initial approval that was announced on May 24, 2022? If so, please specify how many enforcement discretion applications have been approved by FDA, when each application was approved, and the type of enforcement discretion that was granted for each approval.

FDA does not "approve" infant formulas generally or "approve" requests for enforcement discretion. FDA would characterize the information received as a request for enforcement discretion, rather than an application, and the announcement on May 24, 2022, did not represent an approval.

As of May 25, 2022, FDA had responded to one request, asserting our intent to exercise enforcement discretion with regard to infant formula from Kendal Nutricare Ltd. from the United Kingdom, specifically an estimated 2 million cans or 58.1 million estimated full-size 8-ounce bottles of infant formula. We have established a website where we continue to post updates as we respond to requests for enforcement discretion.[5] We encourage parents, caregivers, and healthcare providers to check this site frequently for updates to stay informed on the evolving issue.

b. Has FDA received additional enforcement discretion applications for infant formula? If so, please provide updated numbers regarding how many infant formula enforcement discretion applications the FDA has received, and how many applications for which FDA has exercised enforcement discretion to date.

As noted above, FDA would characterize the information received as a request for

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[3] U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, "Infant Formula Enforcement Discretion Policy: Guidance for Industry," May 2022, available at https://www.fda.gov/media/158476/download.

[4] See U.S. Food and Drug Administration, "Enforcement Discretion to Manufacturers to Increase Infant Formula Supplies," updated continuously, available at https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/enforcement-discretion-manufacturers-increase-infant-formula-supplies.

[5] See U.S. Food and Drug Administration, "Enforcement Discretion to Manufacturers to Increase Infant Formula Supplies," updated continuously, available at https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/enforcement-discretion-manufacturers-increase-infant-formula-supplies.

enforcement discretion, rather than an application.

As of May 25, 2022, FDA had received 26 requests for enforcement discretion and responded to one such request with a letter explaining the conditions under which we intend to exercise enforcement discretion. We update our website as necessary to provide information about responses to additional enforcement discretion requests.[6]

c. What is FDA's goal for how long it takes for an enforcement discretion decision to be made?

FDA reviews each infant formula manufacturer's request and the information they have provided regarding the safety and nutritional adequacy of the product. This includes a review of the infant formula's nutritional composition, ingredients, current or anticipated inventory of the formula, microbiological testing results, and facility inspection history. FDA aims to complete these reviews as expeditiously as possible while also balancing the need to ensure the product is safe and suitable for the U.S. marketplace.

4. Has the FDA issued any new certificates for international suppliers to import infant formula in the U.S. since the infant formula shortage began? If so, how many new certificates has FDA issued and to which companies?

It is unclear what new certificates are being referenced in the question. To the extent "certificates" is a reference to letters of enforcement discretion, as noted previously, as of May 25, 2022, FDA had received 26 requests for enforcement discretion and responded to one such request with a letter describing the conditions under which we intend to exercise enforcement discretion. We update our website as necessary to provide information about responses to additional enforcement discretion requests.[7]

5. According to the Centers for Disease Control and Prevention (CDC), *Cronobacter* bacteria is a germ found naturally in the environment. Can an infant formula manufacturing plant be in compliance with FDA requirements while occasionally finding environmental samples with *Cronobacter*? Why or why not?

Given that *Cronobacter* bacteria are found naturally in the environment, and powdered infant formula is not a sterile product, it is possible for a powdered infant formula manufacturing plant to be in compliance with FDA requirements while occasionally finding environmental samples positive for *Cronobacter*. However, detecting *Cronobacter* in a powdered infant formula

[6] See U.S. Food and Drug Administration, "Enforcement Discretion to Manufacturers to Increase Infant Formula Supplies," updated continuously, available at https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/enforcement-discretion-manufacturers-increase-infant-formula-supplies.
[7] See U.S. Food and Drug Administration, "Enforcement Discretion to Manufacturers to Increase Infant Formula Supplies," updated continuously, available at https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/enforcement-discretion-manufacturers-increase-infant-formula-supplies.

manufacturing facility requires immediate action by the manufacturer given the severe health consequences that can be experienced if product contamination occurs.

It is expected that appropriately designed and implemented environmental monitoring programs would occasionally isolate *Cronobacter* from a powdered infant formula processing environment. Manufacturers of infant formula are required to establish a system of process controls, covering all stages of processing, designed to ensure that infant formula does not become adulterated due to the presence of microorganisms in the processing environment. As part of monitoring these controls, the corrective actions taken to address these findings are critical. In response to these findings, we would expect a firm to conduct a root-cause analysis, conduct cleaning and sanitation activities, conduct verification swabbing, and evaluate if any in-process or finished product was affected. Implementing a routine environmental monitoring program can ensure that the firm is verifying that its cleaning and sanitation procedures are adequate, and it can also assist the firm in identifying any signals for potential deviations in hygienic controls, such as the controlled entry of personnel to the production area or preventing the introduction of unplanned water to dry processing areas. The early detection of *Cronobacter* in the powdered infant formula processing environment and associated corrective actions are important food safety measures to prevent the contamination of powdered infant formula with this environmental pathogen.

6. FDA used two inspectors for the September 2021 inspection of Abbott's Sturgis, Michigan facility, but used 12 inspectors in the January-March 2022 inspection. Why were so many inspectors used for the 2022 inspection?

Typically, one or two investigators conduct facility inspections. However, due to the nature of the confidential informant's allegations as well as the number of complaints tied to product made at the facility and received over a relatively short period, FDA planned a comprehensive inspection involving substantial sampling with a focus on certain issues related to the complaints. Such a complex inspection needed a large, specialized team to investigate the allegations and document any violations.

FDA national experts, with specialized expertise in infant formula, accompanied other food program investigators during this inspection. National experts are senior investigators with several years of experience conducting complex domestic and foreign inspections. In addition, the environmental sampling is a specialized skill and required additional investigators to assist with the sampling.

a. Were all 12 inspectors used on the same day? Please explain in detail the process of the inspection. For example, how many inspectors were used each day, how many worked on writing the report, and what specific assignments were assigned to each individual inspector during the inspection?

The inspection plan did not require that all twelve investigators be present in the facility on the same day. We used a core team of four investigators to perform the inspection and one

investigator to lead sampling activities, and we rotated the other investigators in a day or two at a time to support sampling efforts. One of the investigators did not enter the facility but supported the sampling efforts by procuring needed supplies and transporting materials. The four core investigators served as primary authors of the inspection report. The lead sampler worked on collection reports and ensured that samples were handled properly.

7. Why did FDA notify Abbott of its planned inspection on December 30, 2021, instead of conducting a surprise or unannounced visit?

While FDA generally conducts unannounced domestic inspections, the COVID-19 pandemic required us to rework our business operations so that we could carry out our public health mission while protecting our workforce, and the workforces of those we regulate. These new business operations policies included announcing visits to ensure the safety of both workforces during an inspection. COVID-19 variants, such as the Omicron variant, continued to be prevalent at the time of the January 2022 Abbott Nutrition inspection and impacted both FDA and the industries we regulate. FDA was continuing to pre-announce inspections to protect both FDA's workforce and the workforces of those facilities we inspect. Without our pre-announcement, we would not have known that there was an active outbreak of COVID-19 in the facility.

8. FDA notes in the timeline attached to its testimony that on December 30, 2021, it contacted Abbott to schedule a January 3, 2022, inspection, but Abbott requested a delay due to an ongoing COVID-19 outbreak among its staff. Then on January 27, 2022, FDA contacted Abbott again to announce its intention to proceed with an inspection, but Abbott once again informed FDA of a continued COVID-19 outbreak among its employees. On January 31, 2022, FDA decided to proceed with an inspection of the Sturgis, Michigan plant despite COVID-19 given the fact pattern indicating a potential issue. If FDA ultimately decided to proceed with an inspection despite ongoing COVID challenges at the end of January 2022 – why didn't it just proceed with the inspection in early January or sooner? Why did it wait another month before determining the matter was urgent enough to move forward with the inspection of the Sturgis facility?

We postponed the January 3, 2022, start date to protect the health of our investigators. The inspection required a specialized team of investigators, and the postponement required re-coordination of scheduling. Additionally, we thought the rescheduled January 31, 2022, start date would be enough time for the COVID outbreak to subside in the facility. Despite a worsening of the outbreak in the facility, FDA did not feel comfortable with any further delays once we received an additional complaint in January 2022. Despite the potential health risks, members of the specialized inspectional team volunteered to proceed with the inspection on January 31, 2022.

9. How big is the Abbott facility in Sturgis, Michigan?

Abbott Nutrition's Sturgis, Michigan, facility comprises approximately 30 connected buildings that have been added over time across a 93-acre area.

a. Did FDA collect a sufficient number of samples at Abbott's Sturgis, Michigan facility during the 2022 inspection given the size of the facility?

Yes, FDA used a large sampling team, collected samples of all finished product on site, and collected environmental swabs. In total, we collected 17 sifter tailing samples, 900 finished product samples, and 292 environmental swabs. All samples were collected and tested for *Salmonella* and *Cronobacter*.

10. Based on cursory information, the FDA knew or should have known the impact that eliminating an infant formula manufacturing facility would have on the U.S. infant formula supply. Did the FDA assess the impact that the closure of Abbott's Sturgis plant would have on the overall U.S. supply of infant formula before the decision was made to stop production at the Sturgis facility? If so, what was the result of that assessment, and what if any mitigation plan was put in place by FDA to limit the impact the plant's closure would have on the U.S. infant formula supply? If not, why not?

Prior to the recall and voluntary ceasing of operations at the Sturgis facility, FDA began evaluating supply chain implications, met with USDA, and ensured that U.S. government supply chain partners were engaged. The Agency had to immediately consider the potential impact of a recall of infant formula products on infant health, given that there are multiple supply chains to consider: the supply for healthy infants, infants with allergies, and infants with serious medical conditions. To help mitigate the impacts of the recall and voluntary shutdown, FDA requested that Abbott exempt specialty metabolic products from the recall and instead make the current stock subject to third-party review. FDA also coordinated with groups such as the American Academy of Pediatrics so providers would be prepared to advise parents and caregivers whether switching products was appropriate. Once Abbott Nutrition publicly announced the recall, FDA immediately reached out to all of the other manufacturers to inquire about their ability to increase production capacity. FDA met with Abbott Nutrition in February to discuss whether production could be increased or moved to other Abbott Nutrition locations, and FDAalso began meeting with all of the other infant formula manufacturers about maximizing their capacity to increase production of various infant formulas and mitigate supply disruption. In February, FDA also began expediting entry of imported infant formula meeting FDA's regulatory requirements.

The infant formula supply chain was under stress before the Abbott Nutrition recall and voluntary shutdown began in February. FDA was already working to address these supply chain issues associated with the pandemic by regularly engaging with the Infant Nutrition Council of America to identify challenges caused by the supply chain stress. After the recall, this work intensified and the Agency is working extensively with both Abbott Nutrition and other manufacturers to bring safe products to the U.S. market.

11. The Appendix to FDA's written testimony notes that FDA notified USDA's WIC program of potential action that could impact the infant formula supply on February 11, 2022 – months after the FDA started to receive reports of illnesses possibly linked to Abbott's Sturgis, Michigan facility, and months after it received the whistleblower complaint. This was only four days before FDA recommended that Abbott voluntarily recall product and Abbott voluntarily ceased production at its Sturgis facility, and only six days before Abbott announced its recall of certain products. Why didn't FDA communicate with USDA's WIC program sooner given the impact said recall and plant shutdown would have on the U.S. infant formula market, and WIC consumers?

FDA maintains regular contact with USDA's Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) that predates the current infant formula recall situation. FDA notified USDA's WIC program of this specific potential action that could impact the infant formula supply on February 11, 2022. This was the earliest date that a recall and/or supply chain disruption seemed likely, due to the potentially positive samples, defined as "Cannot Rule Out" (unconfirmed) received on February 9, 2022, from the then-ongoing investigation into the operations at Abbott Nutrition's Sturgis, Michigan, plant.

12. During the hearing, there were multiple statements from FDA's witnesses that FDA needs more data and resources. Regarding the data—the timeline in FDA's written testimony notes that the FDA did not request from IRI (Information Resources, Inc.) infant formula in-stock rates at the national level, which was not previously tracked by FDA, until February 17, 2022—the same day that Abbott announced its recall. Moreover, the timeline notes that the first infant formula data set was obtained by FDA from IRI on February 22, 2022.

a. FDA didn't need additional resources or authority to request and obtain this data, yet it still waited until February to request it. Why does FDA need additional resources or authority if it is not utilizing resources or data that are already available to the agency?

FDA does not have dedicated resources and authority to predict, detect, and respond to supply chain issues for infant formula and medical foods. No law requires manufacturers of infant formula or medical foods to submit data on production levels for their products or develop and make available to FDA risk mitigation plans to proactively identify, prioritize, and mitigate supply chain disruptions. Lacking access to these data, FDA has temporarily procured external data on infant formula in-stock supply rates for use with the FDA 21 Forward Food Supply Chain Continuity system to monitor the availability of infant formula due to the Abbott Nutrition recall and voluntary cessation of production at the Sturgis facility, deferring resources from other critical food safety needs. 21 Forward was initially developed during the pandemic to provide a data-backed understanding of how the pandemic is impacting nodes in the food supply chain from producers and growers to grocery stores. These tools and data sets, particularly at the level of detail and at the speed (e.g., daily/weekly updates) needed, require significant resources, but funding for 21 Forward and the external data sources terminate at the end of FY 2022.

FDA's February 17 request to IRI for national-level infant formula data was just four days after the Agency had sequenced six confirmed samples of *Cronobacter* collected from the Sturgis facility environment. During the four-day period from February 13 to 17, FDA also had multiple calls with Abbott Nutrition about a voluntary recall, in addition to communications with the WIC program, other U.S. government partners, and the American Academy of Pediatrics about the potential for supply chain impacts.

From the beginning of the pandemic, FDA experts were concerned that a disruption at a single infant formula or medical foods facility might lead to a shortage of critical products – particularly specialty metabolic and amino acid formulas. Therefore, the Agency developed and submitted to Congress a legislative proposal in March 2020 requesting supply chain authority for infant formula and medical foods. This legislative proposal was included in the President's Budget for FY 2022 and FY 2023. Although the infant formula and medical foods supply chain legislative proposal has not yet been approved, FDA has leveraged all tools at its disposal to support the supply of safe infant formula products in the wake of the Abbott Nutrition recall and voluntary cessation of production at the Sturgis facility.

b. How would additional resources or data helped FDA collect data that was accessible to it sooner?

To prevent shortages, FDA must be notified earlier about circumstances that could cause a disruption in supply of infant formula and medical foods, including data about production volumes and manufacturers' risk mitigation plans. This would enable us to work quickly with other manufacturers to increase capacity, or to access supply from other facilities. Shortage notifications have been successful for human drugs, which is why we think it is so critical that we also have this authority for infant formula and medical foods.

Additional resources would also allow FDA to invest in data tools to illuminate trends that better identify risk and provide early signals to developing situations so that we can intervene in time to prevent or minimize public health problems. This includes integrating data from additional sources and improving real-time monitoring of the infant formula supply, working with our government partners to the extent resources are available. It is critical to have the right data tools and systems in place to support our experts.

13. With respect to additional resources and staffing—according to a recent letter sent by House Appropriations Chair DeLauro and Congressman Bishop, during FY 2019, Congress funded 2,179 food full-time equivalent (FTE) positions for the Office of Regulatory Affairs (ORA), but ORA allocated only 785 positions for food safety compliance and inspection staff. At the end of the 2019 calendar year, over 100—over 13 percent—of these positions were vacant. During the Subcommittee's hearing, Congressman Bucshon asked why additional resources are needed for staffing if FDA has not even filled the positions it has funding for. In response, you noted that you would follow-up with the specifics and updates on exactly where FDA is. Please provide this information.

As of May 2022, ORA has 89 vacant, funded investigator positions for which FDA is actively recruiting. Of the 89 positions, 31 of these are for food investigators. The expiration of the FDA's Direct Hire Authority in October 2021 has led to a slower pace of hiring.

14. FDA's written testimony notes that hard copies of the whistleblower complaint which were sent to three FDA officials—including Dr. Mayne and Dr. Woodcock—were not forwarded from the FDA mailrooms. Despite the mailroom issues, according to FDA's testimony, some FDA officials did receive the whistleblower complaint in October 2021 whether it be by email or FedEx. And still Dr. Mayne and Dr. Woodcock did not receive copies of the whistleblower complaint until February 2022 via email. Why did it take four months for Dr. Mayne and Dr. Woodcock to receive copies of the whistleblower complaint when others within FDA were already in receipt of the complaint?

Upon receiving the confidential informant complaint on October 21, 2021, FDA immediately assessed the complaint to obtain the facts. We also attempted to gain clarifying information by working with the confidential informant's attorney to schedule an interview. That interview occurred on December 22, 2021.

We are evaluating our processes and their implementation, including how complaints are handled and escalated, and we will incorporate lessons learned to enhance the processes around infant formula and medical foods. FDA will be able to release more information once the internal evaluation is completed.

a. What was the root cause of this communication failure, and who is responsible for this failure?

We are evaluating our processes and their implementation, and we will incorporate lessons learned to enhance the processes around infant formula and medical foods. FDA will be able to release more information regarding communication during the infant formula recall and complaint evaluation once the internal evaluation is completed.

b. What action has FDA taken to prevent such a communication failure from happening in the future?

We are evaluating our processes and their implementation, and we will incorporate lessons learned to enhance the processes around infant formula and medical foods. FDA will be able to release more information once the internal evaluation is completed.

15. If FDA has been treating this issue with a sense of urgency for more than a few weeks, why didn't FDA establish its Incident Management Group (IMG) to work on supply chain and food safety issues until April 1, 2022?

Following its usual procedures, FDA managed the initial illness response through its Office of Coordinated Outbreak Response and Evaluation Network, which spearheads coordination of FDA's foodborne illness response activities and uses an incident command structure similar to those used by incident management groups. With broader supply chain implications in mind, FDA Foods Program leadership also began convening focused discussions on supply chain implications and developed and pursued key actions to address supply chain concerns. Actions included conducting outreach to manufacturers, analyzing data provided by Abbott Nutrition on the products produced at Sturgis, acquiring and analyzing external market data, assessing the U.S. nutritional need for formulas, and exploring options to assist manufacturers with raw material constraints. The group conducting this work included experts and leadership from OFPR, CFSAN, and ORA.

As the incident continued, there was a need for additional support for the existing effort as well as additional expertise from other parts of FDA – particularly additional expertise from CDER on medical needs of populations requiring specialty formula and additional assistance from staff with experience in shortages (an area in which the Foods Program has limited resources since the Foods Program does not have dedicated staff to address shortages). To leverage the additional, Agency-wide resources and in accordance with the FDA Emergency Operations Plan, FDA created an Incident Management Group.

The Honorable Michael C. Burgess, M.D. (R-TX)

1. **Commissioner Califf, due to the COVID-19 pandemic, the FDA conducted routine compliance inspections of Abbott's Sturgis, Michigan facility in September 2019 and September 2021.**

    a. **Should the FDA consider more than one inspection a year on these types of facilities as a preventative action rather than just reacting after babies have already been harmed?**

    FDA considers surveillance inspections of infant formula manufacturers as high priority, and we inspect them more frequently than the three-year frequency required by the FDA Food Safety Modernization Act for domestic high-risk food facilities. Because we recognize the risk associated with these products and the vulnerable population of babies, we typically inspect infant formula facilities every year. All of our surveillance inspections are proactive inspections and are done in addition to any for-cause inspections that are initiated based on complaints and illnesses. Importantly, we have taken lessons learned from this response to potentially modify annual surveillance inspections to include more environmental sampling going forward, while doing so in a manner that minimizes any further disruptions to the supply chain. Any changes to inspection frequency would require additional, dedicated resources.

2. Commissioner Califf, quality management is a critical component of the various industries that the FDA oversees, including diagnostics, drugs, food, and manufacturing. It is critical for the agency and the regulated industry to have a good quality management program to maintain their integrity and trust. We should not be waiting for something to happen and then finding a solution. Instead, we should ensure that policies and procedures are in place to prevent problems from happening in the first place. Especially because once you lose your credibility and trust with the public, it is very hard to gain it back.

a. What kind of policies can the FDA put in place to encourage preventative measures instead of reactive ones in the future?

In the President's FY 2023 budget request, we have identified legislative changes that would provide new tools to help FDA signal those entities who control supply chain dynamics to take action that would prevent or mitigate shortages of infant formula and certain medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or certain medical foods, similar to how drug manufacturers do today. These notifications would allow the Agency to receive indicators about likely or confirmed shortages in the U.S. marketplace, better enabling us to alert the system and stimulate the industry and government partners to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition.

Another component of this proposal would require manufacturers to develop and implement risk management plans. These are routine in most industries and have been used in our drug shortages supply chain oversight. These plans would identify, evaluate, and manage risks to the supply of infant formula or certain medical food. These plans would serve supply chain resiliency within each manufacturer, but they would also be available to FDA for its real-time monitoring efforts of the way they fit together to produce a complete picture of resiliency and vulnerability of this vital supply chain.

None of these improvements would be as useful as a digital platform that monitors the supply chain constantly and in real time. Until such a system is developed, the American public will be vulnerable to threats from natural disasters and cyberattacks as well as the quality problem that created the current infant formula situation.

Another legislative change identified in the President's FY 2023 budget request is access to records in lieu of or in advance of an inspection, or, in other words, the authority to conduct remote regulatory assessments. Presently, FDA has such authority for drug inspections, and the Agency often relies on voluntary participation for remote regulatory assessments of many non-drug establishments. However, reliance on voluntary requests is not sufficient to achieve effective and efficient oversight, as firms can refuse to provide records or other information in advance of or in lieu of an inspection or to participate in remote regulatory assessments. We are seeking to expand the explicit statutory authority in section 704(a)(4) of the FD&C Act to require firms to provide records or other information pertaining to all FDA-regulated products. An expansion across the board, in advance of or in lieu of inspections, would significantly enhance FDA's ability to obtain access remotely to records and other

information for all foods and would help the Agency investigate emerging supply chain issues, promote regulatory compliance, and protect the public health.

b. How can the FDA regain trust with the American people?

FDA intends to regain the trust of the American people. While America's food supply is safe, and our Foods Program experts have significantly contributed to the availability of more nutritious food options for consumers, the program has been stressed by the increasing diversity and complexity of the nation's food systems and supply chain. Fundamental questions about structure, function, funding, and leadership need to be addressed. The Agency's inspectional activities related to the program also need to be evaluated, particularly in light of stresses related to the COVID-19 pandemic. As a result, Commissioner Califf intends to commission external experts to conduct a comprehensive evaluation. We intend to ensure the future Foods Program is maximally effective and lives up to the expectations of the public we serve.

3. Commissioner Califf, the Food and Drug Administration (FDA) decided to inspect the Sturgis, Michigan Abbott facility at the end of January of this year.

a. What led you to do this inspection, the October whistleblower complaint, the reports of infant infections around the same time, or both?

Both the confidential informant's complaint and the case complaints informed our decision to initiate a for-cause inspection of the Sturgis facility. There was no genetic evidence available for FDA to know if the two case complaints in 2021 were linked by whole genomic sequencing, but the case complaints and information from the confidential informant offered an evolving fact pattern that suggested a potential problem at the Sturgis facility that prompted the for-cause inspection.

b. Did you inform Abbott of this whistleblower complaint? If so, when did you notify Abbott of the whistleblower complaint?

No, FDA did not inform Abbott Nutrition of the confidential informant complaint. To protect confidential informants, we do not generally notify a firm of such a complaint. As we did in this case, we follow up with our own, confidential interview(s) of the confidential informant(s) and conduct our own investigation. The information we get from our interviews is incorporated into planning the inspection of the facility.

4. Today, there are hundreds of generic drugs in shortage as well as baby formula. Most recently, contrast dye used for scans is in shortage. Because of that, hospitals are prioritizing patients for scans of tumors and heart conditions.

a. What has the FDA done to address generic drug shortages?

Drug shortages remain a top priority for FDA. While important progress has been made in preventing and mitigating drug shortages, shortages of critically needed drugs remain a

significant public health issue in the United States, and FDA continues to work closely with manufacturers and use all its regulatory tools to address them. In calendar year (CY) 2021, to help increase availability of critically needed medications in shortage, or to prevent potential shortages, FDA leveraged all its applicable regulatory tools. For example, CDER expedited reviews for close to 100 original abbreviated new drug applications (ANDA) and more than 100 ANDA supplements; expedited assessments of manufacturing supplements to facilitate the manufacturing capacity for COVID-19 therapeutic biologics; and exercised regulatory flexibility and discretion in 15 instances to help increase supplies of critically needed medications. During CY 2021, FDA also approved 35 original ANDAs and 86 supplemental ANDAs for drug products frequently used in hospital intensive care units for treatment of COVID-19 patients. These approvals help ensure the adequate supply of these essential products during this time of heightened demand and represent the dedicated efforts of review staff from many offices within FDA. Further information about FDA's efforts to address drug shortages and the tools used are available in the 2021 Report to Congress on Drug Shortages (https://www.fda.gov/media/159302/download).

5. **Commissioner Califf, it has been reported that regarding the contrast dye shortage, the US government is working with Jiangsu Hengrui Medicine in China to alleviate the dye shortage, instead of working with domestic producers. This Chinese manufacturer is known to be affiliated with Chinese military civil fusion projects. Intelligence firms say this company has a risk severity "score" of 7/10 for "Emerging Technology with Dual-Use / Civil – Military Fusion Potential."**

   a. **Is the FDA considering action to prevent foreign manufacturers that have received multiple Warning Letters, especially in China and India, from exporting generic products to the U.S. until the FDA has conducted in-person inspections and ensured these facilities are operating in accordance with FDA regulations?**

When FDA performs an inspection of a foreign drug manufacturer and finds significant violations, FDA takes appropriate regulatory action, which may include issuing a Warning Letter. Additionally, FDA may also place products from a facility on Import Alert.

In many cases, we pursue both a Warning Letter and an Import Alert for drugs manufactured by foreign firms. For example, in FY 2020 and FY 2021, products from more than 70 percent of firms in China and India that were issued Warning Letters were also placed on Import Alert.

After the issuance of a Warning Letter or placing a firm's products on Import Alert for manufacturing deficiencies, FDA usually will conduct an inspection to confirm that corrective actions have been implemented. Only after we verify adequate corrective actions onsite will we then remove the drugs manufactured at that facility from Import Alert for manufacturing deficiencies.