

TESTIMONY
OF
ROBERT M. CALIFF, M.D.
COMMISSIONER OF FOOD AND DRUGS
FRANK YIANNAS, M.P.H.
DEPUTY COMMISSIONER, FOOD POLICY AND RESPONSE
SUSAN T. MAYNE, PH.D.
DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES

FORMULA SAFETY AND SUPPLY: PROTECTING THE HEALTH OF
AMERICA'S BABIES

MAY 25, 2022

RELEASE ONLY UPON DELIVERY

Introduction

Chair DeGette, Ranking Member Griffith, and members of the Subcommittee, thank you for inviting us here today to testify before you on supply disruptions in infant formula. We have all seen the images of empty store shelves and heard the stories of parents of kids unable to find the food their children need to survive. This situation is unacceptable. The staff at the U.S. Food and Drug Administration (FDA or the Agency) feel this not just as public servants whose job it is to ensure that these critical products are safe and nutritious, but also as parents and grandparents. Our top priority now is addressing the dire need for infant formula in the U.S. market, and our teams are working night and day to help make that happen.

At the same time, we have begun an after-action review to evaluate our own performance. We appreciate the opportunity to discuss conditions at the Abbott Nutrition facility in Sturgis, Michigan, which led to the recall that contributed to the current supply disruptions; our infant formula supply chain monitoring and mitigation efforts; and additional tools necessary if we are to prevent, monitor, and mitigate any future infant formula supply disruptions.

Inspection of Abbott Nutrition's Sturgis, Michigan, Facility

On September 20, 2021, FDA learned of a *Cronobacter* infection in an infant who reportedly consumed powdered infant formula produced at Abbott Nutrition's Sturgis, Michigan, facility. FDA immediately reported this case to Abbott Nutrition and immediately followed up on the complaint, including testing formula associated with this case complaint. No *Cronobacter* was recovered from the product after FDA testing.

On November 17, 2021, FDA received a complaint involving an infant with *Salmonella* infection. FDA and our partners at the Centers for Disease Control and Prevention (CDC) eventually determined this event was unrelated to the other cases.

FDA received the second complaint involving an infant with *Cronobacter* infection on December 1, 2021. We again collected intact samples of powdered formula; no *Cronobacter* was recovered. We also notified Abbott Nutrition about this case.

Because *Cronobacter* is not a nationally reportable disease, isolates of the pathogens had not routinely undergone genomic analyses, as would occur with pathogens like *Salmonella*. In 2021 there was no genetic evidence available for us to know if these two cases from 2021 were linked by whole genome sequencing.

But given the two case complaints and the potential severity of *Cronobacter* infections, along with a complaint from a former employee at the Sturgis facility, on December 6, 2021, FDA initiated inspectional planning for a for-cause inspection at the Sturgis facility with an anticipated inspection date in early January 2022. We notified Abbott Nutrition of the planned inspection on December 30, 2021. Abbott Nutrition responded by notifying FDA of approximately a dozen COVID-19-positive employees in its facility. Although we delayed our inspection temporarily because of these COVID-19 infections, FDA commenced our inspection on January 31, 2022.

FDA received a third report of an infant *Cronobacter* illness on January 11, 2022, while the facility's COVID-19 outbreak delayed FDA's inspection. Again, FDA tested product associated with this illness, found no *Cronobacter*, and notified Abbott Nutrition.

FDA learned of a fourth case of *Cronobacter* infection on February 17, 2022, the date on which Abbott Nutrition initiated a voluntary recall and FDA issued a consumer advisory.

Infants in all four cases were hospitalized, and *Cronobacter* may have contributed to deaths in two cases. All of the infants are reported to have consumed powdered infant formula produced at Abbott Nutrition's Sturgis facility. The Agency investigated each complaint and analyzed product from the consumers' homes when available. FDA also notified Abbott Nutrition after receiving each complaint.

The CDC receives reports on foodborne disease outbreaks from state, local, and territorial health departments. On average, CDC receives two to four *Cronobacter* case reports annually; however, because *Cronobacter* infection is not reportable in most states, the total number of cases that occur in the United States each year is not known. Thus, the four cases that came to our attention between September 20, 2021, and February 17, 2022, raised concerns. Despite this very unusual combination of events, we do not have definitive evidence proving that insanitary conditions of the Sturgis facility actually caused the *Cronobacter* illnesses of these infants.

We have included this timeline in Appendix A, and we have processes under review to develop better systems within FDA.

In sum, awareness of the four *Cronobacter* cases offered an evolving fact pattern, leading us to initiate a for-cause inspection, but our inspection dramatically altered the fact pattern.

Sanitary environmental conditions and well-maintained equipment are the most basic, minimal conditions needed for a manufacturer to produce dry powdered infant formula that is free of bacterial contamination. The FDA inspection team observed significant operational deficiencies in Abbott Nutrition's Sturgis facility during the January 2022 inspection. The totality of evidence obtained during our inspection caused FDA to conclude that infant formulas produced at this plant were produced under insanitary conditions and may be contaminated with *Cronobacter*. We based our conclusions on the following evidence:

- FDA investigators collected multiple samples from swabs in the facility's environment, which later tested positive for *Cronobacter sakazakii*.
- FDA investigators observed serious cracks in the firm's spray dryers, key pieces of equipment for producing powdered products and an issue that has been linked to at least one historical foodborne illness outbreak in powdered infant formula at a different facility.
- FDA investigators also found water leaks and condensation, which are risk factors for *Cronobacter*, in areas where dry powdered formula was produced.
- Employees in the facility lacked adequate handwashing technique.
- A review of the firm's internal records also indicated environmental contamination with *Cronobacter sakazakii* and the firm's destruction in 2019 and 2020, respectively, of two batches of finished product due to the presence of *Cronobacter*.

- FDA investigators noted that Abbott Nutrition did not 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 formula or in the processing environment.
- FDA also noted that Abbott Nutrition did not ensure that all surfaces that contacted infant formula were maintained to protect infant formula from being contaminated by any source.

FDA investigators collected numerous product and environmental samples during the inspection. Product samples FDA collected at Abbott Nutrition's Sturgis facility and analyzed for *Cronobacter* tested negative. It is well documented in the scientific literature, however, that end product testing is unlikely to detect low levels of contamination. In contrast, five environmental subsample surface swabs collected from the facility tested positive for *Cronobacter sakazakii*; four of these instances of contamination were detected by FDA-initiated testing, and one was detected through simultaneous firm-initiated testing. The positive *Cronobacter sakazakii* environmental samples collected at Abbott Nutrition's Sturgis facility have been analyzed using whole genome sequencing, revealing five different strains of *Cronobacter sakazakii*. While none of these environmental samples matched the limited (two) clinical samples from infants ill with *Cronobacter*, these findings remain a serious concern, as environmental sources of *Cronobacter* in infant formula manufacturing plants have been identified as one of the most likely sources of contamination.

As soon as the Agency received these positive environmental sampling results in February 2022, we communicated with Abbott Nutrition about the need for the firm to issue a voluntary recall. Abbott Nutrition voluntarily ceased production at the Sturgis facility two days prior to the recall, and FDA supported this decision given the insanitary conditions at the facility. On February 17, 2022, we issued a public communication advising consumers not to use the affected products. Abbott Nutrition initiated a voluntary recall the same day.

Insanitary conditions of this kind are unacceptable in all food manufacturing facilities, but especially in areas producing dry powdered formulas that serve as the sole source of nutrition for infants. Finding pathogens in finished product during routine testing also generally indicates a potentially serious loss of sanitary process control during manufacturing. FDA would expect any manufacturer with a robust quality assurance program to identify and quickly take corrective action when such conditions are present.

FDA knew that restarting the Sturgis, Michigan, facility was critical, because it was one of three plants run by a company with the largest market share, and many of its specialty formula products cannot be quickly manufactured at other facilities. We also became aware that Abbott Nutrition lacked a contingency plan to produce its lines of specialty metabolic and amino acid formulas that serve as a sole source of nutrition for thousands of infants with metabolic disorders. We lost confidence that Abbott Nutrition had the appropriate safety and quality culture and commitment to fix these problems quickly. FDA was left with limited options. Given the market share that Abbott Nutrition had for regular and critically needed specialty metabolic and amino acid formulas, FDA decided to negotiate a consent decree with the company rather than seeking a court order of permanent injunction through a contested process. A consent decree was the best option, giving FDA more control over the outcome, and was more likely to result in a safe resumption of operations by Abbott Nutrition at the Sturgis facility.

With the urgent public health need in mind, FDA, along with the U.S. Attorney's Office for the Western District of Michigan, moved as quickly as possible through the negotiation process. In fact, the process here was shorter than it often is for obtaining a consent decree. FDA made clear its expectations for a safe reopening of the facility. Even still, because it was a negotiation process with a regulated firm, the U.S. government did not completely control the timeline. Moreover, FDA's negotiations needed to be informed by our inspection of the Sturgis facility, which did not close until March 18, 2022, to ensure that the consent decree would fully address all observed violations.

FDA's and U.S. Government Actions to Increase the Supply of Specialty Metabolic Formulas

When we talk about the infant formula supply chain, we really need to consider multiple supply chains, including, but not limited to, the supply of infant formula for healthy infants, another for infants with allergies and/or medical conditions who need hypoallergenic amino acid formulas, and another for infants who have very serious medical conditions, such as inborn errors of metabolism, and require unique specialty metabolic formulas. Abbott Nutrition dominates the market for many of the amino acid-based and metabolic formulas. Unfortunately, the only site where Abbott Nutrition produces these critical products is the Sturgis plant. Thus, the Agency immediately had to consider the potential impact a recall of these specialty formulas could have on infant health.

FDA decided to exempt specialty metabolic products from the recall and required that the current stock of these formulas in storage would be subject to third-party review before release. Some of the infants who were using these non-recalled products could potentially be switched to comparable products, but transitioning is not always well tolerated or possible and thus requires clinical input from the child's health care provider. For this reason, we coordinated with groups such as the American Academy of Pediatrics, Genetic Metabolic Dietitians International, and the Society of Inherited Metabolic Disorders so providers would be prepared to advise their patients whether switching products was appropriate. We also coordinated with the U.S. Department of Agriculture's (USDA) Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), and made them aware of the pending recall in advance of it occurring. To help support supply chains, our infant formula team had to determine for each of these products what comparable products might exist from other infant formula manufacturers and request that they increase production of these products as much as possible. These efforts included seeking available inventory outside of the domestic market.

FDA worked with Abbott Nutrition to identify and prioritize specialty and metabolic formulas and asked Abbott Nutrition to establish a process to provide these formulas to those in need on a case-by-case basis. After the third-party audit concluded, Abbott Nutrition began releasing these critical products on a case-by-case basis. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA determined that the case-by-case release of these priority products is the best solution prior to resuming production of them at Abbott Nutrition's Sturgis facility. Since Abbott Nutrition did not have a plan or any capability to produce these critical, lifesaving products at another of their facilities, case-by-case release was the only option. FDA continues to use all levers we have, including Operation Fly Formula, to be able to increase the supply of these formulas, which come from an even more limited set of manufacturers than general infant formula. The first airlifts of infant formula as part of Operation Fly Formula are amino acid and hypoallergenic hydrolyzed formulas that are most critically needed. We note that having access to good data on the availability of specialty and metabolic formulas is challenging; measures useful to assess the supply of general formula such as those from Information Resources Inc.

(IRI) (discussed below), are not informative for these products, as they are not always sold in traditional retail settings.

FDA's Work with Partners to Increase the Broader Infant Formula Supply

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall began on February 17, 2022. Abbott Nutrition's voluntary recall and subsequent voluntary cessation of operations at its Sturgis plant in February further destabilized the infant formula supply chain. Prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Our efforts to help support an all-of-government supply chain response included regular engagement with the Infant Nutrition Council of America (INCA), and its members, to identify challenges they were facing. Beginning immediately after the recall in February, this work greatly intensified, and the Agency has been working extensively with Abbott Nutrition and other manufacturers to bring safe products to the U.S. market as quickly as possible.

FDA's intra-agency group includes experts from the Office of Food Policy and Response (OFPR) and the Center for Food Safety and Applied Nutrition (CFSAN). They began evaluating infant formula supply chain implications prior to the recall, met with USDA, and ensured that U.S. government supply chain partners were engaged at the highest levels. FDA and USDA, as co-leads for Food and Agriculture Sector Risk Management, provided regular updates to the White House regarding overall supply chain concerns, including information about infant formula. Since the first day, FDA has worked tirelessly with U.S. government partners to mitigate the supply chain disruption for both regular and specialty formulas.

It is important to understand that only facilities experienced in and already producing infant formula and specialty metabolic products are in a position to make products that would not pose significant health risks to consumers. Infant formulas for healthy, full-term infants are complex in terms of formulation, processing, and other considerations to achieve required levels of 30 different nutrients and to avoid excessive levels of 10 nutrients that can be toxic when levels are too high. Formulas for low birth weight or premature infants, or those with serious health conditions, are even more complex; for example, hypoallergenic formulas need to be manufactured to ensure cross-contact with other formulas made in a facility does not occur.

FDA continues taking key steps to help increase the supply of infant formula in the United States. FDA is leveraging all tools at our disposal to support the supply of infant formula products:

- Meeting regularly with major infant formula manufacturers to better understand and maximize their capacity to increase production of various types of infant formulas and essential medical foods. The infant formula industry is already working to maximize their production to meet new demands. Efforts already underway by several infant formula manufacturers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly specialty formulas.
- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 Forward food supply chain continuity system, combined with external data. Originally designed to address the broader

food supply during the pandemic, FDA has adapted 21 Forward to monitor and support infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales.

- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Implementing a new process to temporarily exercise enforcement discretion, on a case-by-case basis, for certain requirements that apply to infant formula. These flexibilities, applicable to both imported and domestically produced infant formula, will augment supply volume while meeting FDA's criteria for labeling, nutrition standards, and safety testing. Within a week, FDA informed two foreign manufacturers that they could use this pathway to import their infant formula, and we are evaluating multiple other promising requests.
- Expediting the necessary certificates to allow flexibility in the movement of already permitted products from abroad into the United States.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues to help increase volume of product available as quickly as possible.
- Continuing outreach to retailer stakeholder groups to request that their members consider placing purchase limits on some products to protect infant formula inventories for all consumers.

In broader whole-of-government efforts, agencies are working together to improve the supply of infant formula to American families by:

- Invoking the Defense Production Act, directing firms to prioritize and allocate the production of key infant formula inputs to help increase production and speed up supply chains.
- Launching Operation Fly Formula, coordinating the Department of Health and Human Services and U.S. Department of Agriculture (USDA) to leverage Department of Defense contracts with commercial air cargo lines to pick up overseas infant formula that meets U.S. health and safety standards, so it can get to store shelves faster. Bypassing regular air freighting routes will speed up the importation and distribution of formula and serve as an immediate support as manufacturers continue to ramp up production.
- Offering state health commissioners flexibilities through WIC to determine products that may be substituted for recalled products, allow families to purchase different container sizes and physical forms, allow purchase of noncontract brands, and waive retailer minimum stocking requirements to allow formula to transfer to where it is most needed. We thank Congress for passing the Access to Baby Formula Act of 2022 to expand access to baby formulas for certain American families during this supply chain disruption, but we know that still more remains to be done to ensure industry consolidation and sole-source purchasing contracts do not put future American families in this situation again.
- Addressing price gouging and unfair market practices by calling on retailers to issue purchasing limits, as well as engaging with state attorneys general to encourage them to use their power to monitor and act on price gouging and predatory behavior. In addition, the Administration has

asked the Federal Trade Commission to use all of its available tools to monitor and investigate illegal and predatory conduct.

FDA has been working closely with all major infant formula manufacturers to mitigate supply disruption. All manufacturers already in the U.S. market have increased production to capacity. However, FDA lacks authority, resources, or dedicated staff to predict, detect, and respond to supply chain issues for infant formula and medical foods – although we have requested authority to do so since 2020, including in our fiscal year (FY) 2022 and FY 2023 budget requests. FDA developed this legislative proposal because we were well aware that the U.S. infant formula supply chain was dominated by a small number of actors with only a handful of manufacturing facilities – making it at high risk for disruption by any single event or stressor. Even without the authorities to compel submission of supply chain data, FDA took numerous steps to request these data and shore up supply to the extent we received cooperation of firms.

Following FDA’s efforts, the major infant formula manufacturers are producing at increased capacity and have been further optimizing their lines to produce more infant formula to meet current demand. In the month of April, consumers purchased more infant formula than they did in the four weeks prior to the recall, which is a good indication that powdered infant formula availability is headed in the right direction. Data from IRI show nearly 80 percent in-stock rates for the week ending May 15, 2022, (compared to 89 to 90 percent in-stock rates before the Abbott Nutrition recall; see figure 1). This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate translates to 40 of those 50 product types being available. But we understand – as parents and grandparents ourselves – that many have been unable to access the products they need and that they are understandably frustrated and anxious.

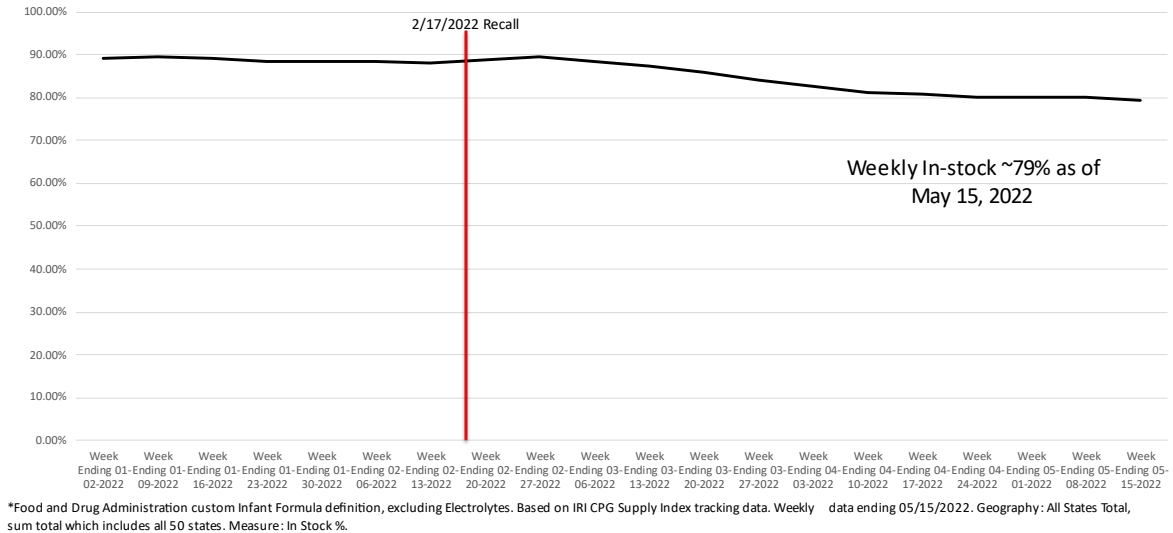
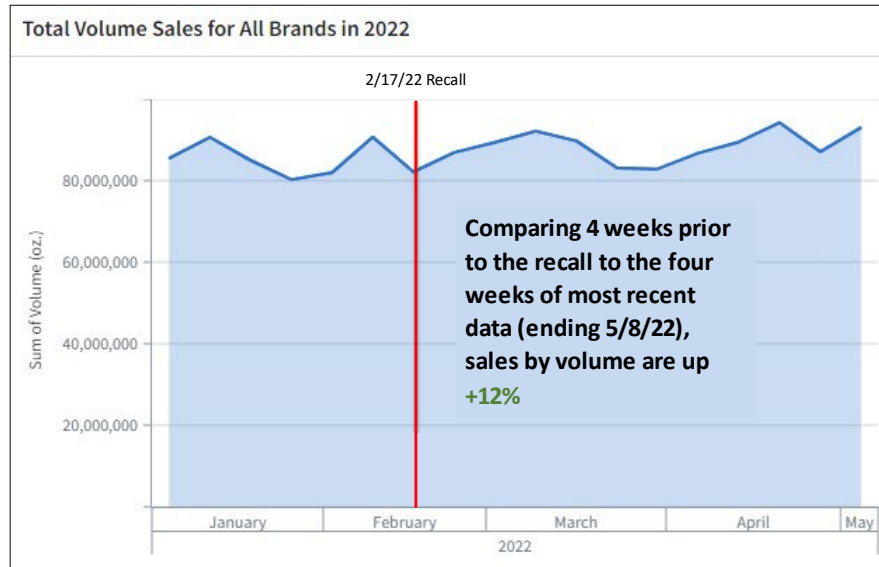


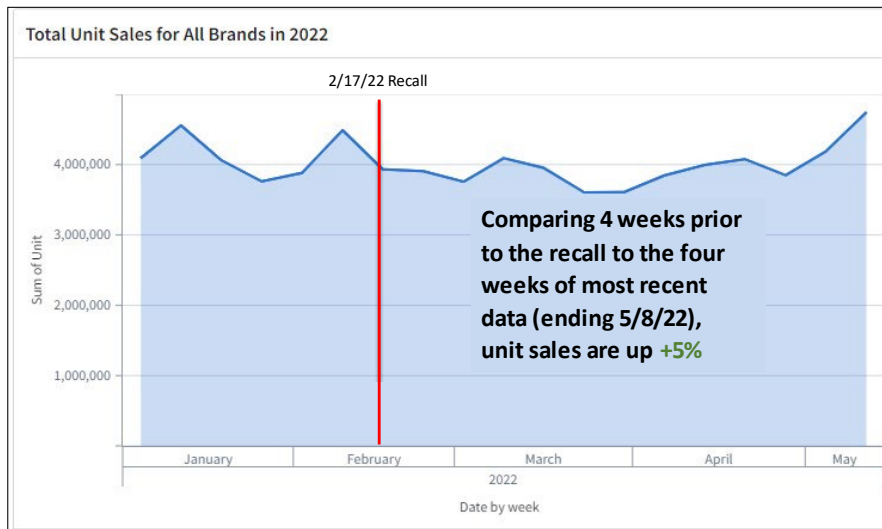
Figure 1: National In-stock Rate 2022 Year-to-Date: Infant Formula

While in-stock rates have dropped gradually because of Abbott Nutrition’s inability to resume production as quickly as we all would like, there are some positive trends because of FDA’s call to action to the rest of the industry. National infant formula sales by volume for the most recent four weeks of data through May 8, 2022, increased 12 percent compared to the four weeks prior to the recall (see figure 2). And national infant formula sales by unit increased 5 percent for the most recent four weeks of data through May 8, 2022, compared to the four weeks prior to the recall (see figure 3).



**Food and Drug Administration custom Infant Formula definition, excluding Electrolytes. Based on IRI POS data, data ending 05/08/2022 as compared to 4 weeks ending 2/13/2022, Geography: Total US - Multi Outlet + Conv Measure: Volume Sales.

Figure 2: Total National Volume Sales Infant Formula 2022 Year-to-Date



*Food and Drug Administration custom Infant Formula definition, excluding Electrolytes. Based on IRI POS data, data ending 05/08/2022 as compared to 4 weeks ending 2/13/2022, Geography: Total US - Multi Outlet + Conv Measure: Unit Sales.

Figure 3: Total National Unit Sales Infant Formula 2022 Year-to-Date

Through our weekly intensive discussion with manufacturers, we also know that all producers that supply the U.S. market have already stepped up to the challenge and are telling us they are producing at an expanded capacity. For example, Nestle Gerber increased the amount of its infant formula available to consumers by approximately 50 percent in March and April, and Reckitt is supplying more than 30 percent more product so far this year.

What these data tell us collectively is that while there is more product being produced and sold, it is of less variety than prior to the recall. These metrics also indicate that we are on a positive trajectory. However, we know that one parent not being able to find the products they want is one parent too many, and we, also, have seen the photos of empty shelves and heard of the stressful stories of parents having to work extra hard to find product. This is unacceptable.

Importantly, we know that some data suppliers who use less standardized metrics have reported lower in-stock rates, and we believe those news reports, recited without validation, may have exacerbated the situation in recent weeks. Throughout the pandemic, retailers have experienced a new type of consumer behavior – which we can appreciate and understand – where consumers may purchase additional units to ensure they can stock their pantries, because of a loss in confidence that their desired products will be available during their next grocery shopping trip. And when it comes to ensuring their infants have access to a sole source of nutrition, this behavior is understandable.

As discussed above, data available to FDA show that volume sales of infant formula, as a category, are currently higher than they were before the Abbott Nutrition recall. However, there have been dramatic shifts in which products (e.g., brand, type, and size) are being sold, and the recent increases in consumption create empty shelves that require further ramp up of supply. In addition, there are significant concerns related to the availability of certain specialty formula products, such as amino acid-based products and formulas for individuals with inborn errors of metabolism – these are products on which FDA has been especially focused. Indeed, the availability of specialty and metabolic formulas remains a fluid and evolving situation.

The Agency's best current assessment is that with all of the current actions, and the potential for Abbott Nutrition's Sturgis facility to resume production safely in the near term, the supply of infant formula will continue to improve over the next several weeks. In the meantime, FDA is encouraged to see that as of early May, the amount of infant formula sold in the United States continues to rise.

On May 16, 2022, the U.S. District Court for the Western District of Michigan entered a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott Nutrition principals. Under the consent decree, Abbott Nutrition has agreed to take corrective actions following FDA's inspection of its Sturgis, Michigan, facility. The consent decree obligates Abbott Nutrition to take actions that are expected to ultimately result in an increase of infant formula products, while ensuring that the company undertakes certain actions that would ensure safe powdered infant formula is produced at the facility. When the company restarts production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem, and conduct a root-cause investigation before resuming production.

Modernizing Infant Formula Safety and Supply Chain Security

We take seriously our duty to prevent and respond to foodborne illnesses and food contamination events. FDA will be conducting an evaluation of our response to this incident and determine what additional

steps should be taken to ensure the maximum effectiveness of Agency programs and policies related to infant formula and medical food complaints, illnesses, and recalls.

More than 3.5 million babies are born in the United States each year, many of whom rely on formula at some point as their sole source of nutrition. FDA has nine staff devoted to reviewing infant formula premarket submissions for safety and nutrition. Even before the voluntary recall and production halt at Abbott Nutrition's Sturgis facility, FDA's infant formula staff faced increased workload due to COVID-19 supply chain issues and increased product innovation in the infant formula industry. Furthermore, the war in Ukraine has caused a disruption in the supply of sunflower oil, an ingredient in many formulas, which has further increased FDA's review responsibilities as manufacturers assess their supply chains and needs to reformulate product. Recent actions to increase imports will also increase FDA's workload, as the review team must review incoming applications and collaborate with the food safety team to ensure that these products are both safe and nutritionally adequate.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscore the risks and vulnerabilities in the supply chain when production is consolidated among few major manufacturers utilizing few manufacturing facilities. Building resiliency across the infant formula supply chain will better enable the industry to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long term. Recommendations from the White House's 100-day supply chain review report¹ with regard to pharmaceutical and active pharmaceutical ingredient supply chain resiliency may prove insightful here. In partnership with other agencies across the U.S. government, we also hope to initiate a broad dialogue on how contracting models for these products could be enhanced to incentivize greater resiliency for infant formula supply, encourage new entrants into the market, and diversify the supply chain, without adversely impacting programmatic costs and the number of infants served by the WIC contract models.

While infant formulas – and particularly specialty and metabolic formulas – are regulated by FDA as food, they are in many ways comparable to life-saving medications. Viewing these products through the lens of how FDA addresses drug shortage monitoring and mitigation supports the need for a more responsive mechanism to monitor for and mitigate against potential supply chain disruptions. FDA's foods regulatory program has and can continue to benefit from the expertise and experience available within the Agency's medical product centers in this regard. The importance of a team with clinical, nutritional, and analytical expertise cannot be emphasized too much.

Strengthening data and technology tools at FDA and other agencies is also critical to enhancing infant formula supply chain resiliency. The industry has sophisticated supply chain data enabling modeling and predictive analytics for the individual manufacturers and suppliers, but there is no data system to combine the information into a composite picture that would enable an understanding of the resiliency of the entire system to stresses, disruptions, and changes in demand. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. A dynamic, interconnected supply chain monitoring platform and robust data

¹ The White House, *Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-based Growth: 100-day Reviews under Executive Order 14017*, June 2021, available at <https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf>.

sets are necessary to enable the Agency to be most effective in monitoring food supply chains, managing risks, and identifying and quickly addressing supply chain disruptions to reduce impacts on consumers.

One example of a beginning to this effort is FDA's 21 Forward platform, which has been essential to our infant formula supply chain efforts. Further development of the technology will allow us to integrate, analyze, and monitor multiple data sets – including data on consumer purchasing, in-stock product availability, food facility registration, and imports – in real time to inform our response and help us focus on the areas of greatest need.

In the President's FY 2023 budget request, we have also identified legislative changes that would provide new tools to help FDA signal our partners who control supply chain dynamics to take action that would prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, similar to how drug manufacturers do today. These notifications would allow the Agency to receive relatively imprecise – but helpful – 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 be requiring 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 essential 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. This industry and most others have been resistant to efforts to develop such a system, but until such steps are taken, 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 Federal Food, Drug, and Cosmetic 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 from facilities producing infant formulas and essential medical foods, and would help the Agency investigate emerging supply chain issues, promote regulatory compliance, and protect the public health.

Conclusion

Ensuring the availability of safe, sole-source nutrition products like infant formula is of the utmost importance to FDA. Our teams have been working tirelessly with all the responsible entities across government to address and alleviate supply issues while protecting safety, and we will continue doing everything within our authority to ensure the production of safe infant formula products.

Thank you, and we look forward to answering any questions you may have.

Appendix A: Timeline of Infant Formula Recall and Supply Chain Disruption

Summary

Below is the timeline associated with ongoing stressors on the infant formula supply chain and FDA's investigation and response to complaints associated with and conditions at Abbott Nutrition's Sturgis, Michigan, facility.

In this investigation, FDA received a total of five case complaints (four *Cronobacter* cases and one *Salmonella* case). Of these complaints, four were received prior to FDA's January 2022 inspection (three *Cronobacter* cases and one *Salmonella* case). FDA and CDC later determined the *Salmonella* case to be unrelated to the Abbott Nutrition facility. FDA had clinical isolates for only two of the *Cronobacter* cases. Investigating case complaints takes time – product samples are taken, interviews are conducted, records are collected, and pathogens are sequenced. In three of the *Cronobacter* case complaints, the product samples taken during the case investigations all tested negative for *Cronobacter*. However, as FDA received additional complaints and associated details over time, a pattern emerged that suggested a potential problem at the Sturgis facility. The timeline below sets forth the actions that FDA took to investigate these cases and Abbott Nutrition's Sturgis facility, as well as to obtain agreement from the company to cease production and enter into a consent decree containing a legally enforceable path forward to resume safe operations at the facility.

FDA has taken aggressive action to attempt to address the infant formula supply chain issues. Days after the World Health Organization declared COVID-19 a pandemic, FDA experts became concerned that a disruption at a single infant formula or medical foods facility could lead to a shortage of critical products – especially specialty metabolic and amino acid formulas. FDA developed and submitted to Congress a legislative proposal in March 2020 requesting supply chain authority. Despite not receiving such authority nor having dedicated resources, FDA stood up a system to monitor potential food supply chain disruptions, 21 Forward, which was funded by Acting Commissioner Janet Woodcock out of Office of the Commissioner's reserve funding.

Prior to Abbott Nutrition's voluntary recall, FDA began having supply chain discussions with our federal partners and stakeholders, and these continued on a frequent basis. FDA ensured specialty metabolic formulas at Abbott Nutrition were excluded from the recall, held, and made available for those in critical need. Just after the recall, for example, FDA engaged with the relevant infant formula manufacturers to begin regular conversations about bolstering production and supply.

This timeline demonstrates areas where FDA can and must do better or be faster. A detailed internal review is ongoing to determine what process, policy, and authority changes can improve FDA's response to infant formula investigations and recalls. For example, the FDA investigator who performed the September 2021 inspection at the Abbott Nutrition facility followed standard process to search for associated case complaints days prior to inspection, and thus during the inspection was unaware of the first *Cronobacter* complaint that FDA received. If FDA had modernized IT systems that could have instantly linked the first *Cronobacter* complaint to the IT system the investigator was using during the inspection, it is likely FDA's timeline would look very different.

However, FDA's investigation was impacted by events not fully in the Agency's control, such as the emergence of the omicron variant that likely led to an outbreak of COVID-19 cases at the Sturgis plant that resulted in the delay of this inspection. Since *Cronobacter* is not a reportable pathogen, FDA is not

able to know if clinical cases share the same pathogen, suggesting a point source, and there is not a robust database of sequenced samples, which meant that FDA is not able to make rapid comparison of clinical, product, or environmental samples during an investigation to determine whether matches exist that can link a product or facility to an illness. There was also delay in the confidential complainant's availability to meet with FDA. And while FDA pursued the consent decree as quickly as possible, FDA does not have control over how quickly negotiations resolve.

FDA's path forward is informed by our experience. Even while responding to this supply chain crisis, we are working to improve our agency to make sure that we are protecting the most vulnerable members of our society. We are committed to coming back to this Committee after our review is complete to share more details on the ways we believe that FDA can improve our processes and programs, as well as any areas where we may need the Committee's support for additional authorities or resources.

Timeline of infant formula related activities

2020

- **11 March 2020** – World Health Organization declares COVID-19 a pandemic.
- **16 March 2020** – FDA begins to have concerns about infant formula and special medical food shortages given their production at a small number of facilities controlled by a handful of firms. FDA identifies a need for supply chain authorities and begins to draft a legislative proposal.
- **21 March 2020** – FDA submits a legislative proposal to Congress requesting supply chain authority for infant formula and special medical foods.
- **September 2020** – FDA stands up a proof-of-concept food supply chain monitoring system called 21 Forward to monitor the food supply chain for disruptions despite lack of dedicated funds or authorities. FDA initially uses the system to monitor for supply chain disruptions related to COVID-19, including infant formula-related disruptions. For example, we contacted an infant formula plant in a COVID rapid riser community in an attempt to minimize disruption.

2021

- **June 2021** – FDA requests infant formula and special medical food supply chain authorities in its FY 2022 budget request. FDA also requests funding for four additional infant formula staff.
- **20 – 24 September 2021** – FDA conducts a routine surveillance inspection at Abbott Nutrition's Sturgis, Michigan, facility. The FDA investigator searched the Agency's database for related consumer complaints days prior to inspection. FDA made five observations – including standing water and inadequate handwashing.¹
- **20 September 2021** – FDA receives a consumer complaint report of *Cronobacter* illness in an infant from the Minnesota Department of Health (Case Complaint #1). The illness onset was 6 September 2021.
- **21 September 2021** – FDA informs Abbott Nutrition of the *Cronobacter* complaint it received (Case Complaint #1). Minnesota Department of Health sent product samples to CDC for sequencing earlier in September.
- **23 September 2021** – FDA collects product samples from the hospital where the patient was treated. The sample was sent to FDA's Southeast Food and Feed Laboratory for analysis (Case Complaint #1).
- **6 October 2021** – FDA's Southeast Food and Feed Laboratory reports no *Cronobacter* findings in samples (Case Complaint #1).
- **10 October 2021** – Minnesota Department of Health sends patient clinical sample to CDC (Case Complaint #1).

¹ U.S. Food and Drug Administration, "Form 483: Inspectional Observations; Abbott Nutrition, Sturgis, Michigan Facility," September 20-24, 2021, available at https://www.fda.gov/media/156747/download?utm_medium=email&utm_source=govdelivery.

- **21 October 2021** – FDA receives a complaint from a confidential informant electronically. Complaint is reviewed by multiple FDA staff. FDA acknowledges receipt. FDA begins planning for an inspection at Abbott Nutrition’s Sturgis facility.
- **26 October 2021** – FDA Detroit District Office receives a hard copy of a complaint from a confidential informant. FDA leadership do not receive direct copies of the complaint due to an isolated failure in FDA’s mailroom, likely due to COVID-19 staffing issues.

FDA Staff in Receipt of Complaint; Dates of Receipt	
William Weissinger (Office of Human and Animal Food Operations-East Division 6, District Director, Office of Regulatory Affairs (ORA))	21 October 2021 – Received via email 26 October 2021 – Received via FedEx
Dr. Andrea Lotze (Medical Director, Infant Formula and Medical Foods Staff, CFSAN)	20 October 2021 – Received via email*
Cathy Hermsen (Assistant Commissioner for Criminal Investigations, ORA)	3 November 2021 – Alerted to existence by FDA staff 5 November 2021 – Received via USPS (FEDEX package with complaint)
Dr. Judith McMeekin (Associate Commissioner for Regulatory Affairs)	14 February 2022 – Received via email (forwarded from FDA staff)*
Dr. Susan Mayne (Director, CFSAN)	14 February 2022 – Received via email*
Dr. Janet Woodcock (then-Acting FDA Commissioner)	14 February 2022 – Received via email (forwarded from FDA staff)*
*Hard copies addressed to these individuals were not forwarded from the FDA mailrooms, likely due to COVID-19-related mail routing issues. In May 2022, the CFSAN mailroom located copies of the complaint sent to Susan Mayne and Andrea Lotze via FedEx and forwarded to these individuals. The copies of the complaint sent via FedEx to Judith McMeekin and Janet Woodcock have not been located to date but a mailroom analysis is underway.	

- **4 November 2021** – FDA Office of Human and Animal Food Operations (OHAFO) staff discuss confidential informant complaint with FDA’s Office of Criminal Investigations.
- **8 November 2021** – FDA OHAFO staff discuss confidential informant complaint with the investigator and National Expert Investigator (whose expertise includes infant formula and medical food inspections) who inspected Sturgis facility in September 2021.
- **17 November 2021** – FDA receives a consumer complaint of a *Salmonella* illness potentially associated with an Abbott Nutrition powdered infant formula. After investigation, CDC and FDA eventually rule this case as unrelated to Abbott Nutrition.
- **1 December 2021** – FDA receives a consumer complaint of a *Cronobacter* death potentially associated with Abbott Nutrition powdered infant formula (Case Complaint #2). The date of illness onset was 20 November 2021. No positives for *Cronobacter* were among formula samples collected by FDA for follow-up testing.
- **2 December 2021** – FDA notifies Abbott Nutrition of the *Salmonella* and second *Cronobacter* consumer complaints (as previously noted, FDA and CDC later decide the *Salmonella* case is not related to Abbott Nutrition). FDA collected and analyzed product samples but did not find *Cronobacter* or *Salmonella*. No clinical isolate was available for the *Cronobacter* case.
- **7 December 2021** – FDA requests to interview the confidential informant, but due to scheduling limitations associated with the informant, the interview was not scheduled until 22 December 2021.

- **22 December 2021** – FDA interviews the confidential informant. This information informs the inspection that occurs in January 2022.
- **30 December 2021** – FDA contacts Abbott Nutrition to schedule a 3 January 2022 inspection pursuant to the Agency’s policy to preannounce inspections during the COVID-19 pandemic. Abbott Nutrition requests FDA delay the inspection due to an ongoing COVID-19 outbreak among its staff. FDA agrees to a delay.

2022

- **11 January 2022** – FDA receives a third *Cronobacter* illness complaint (Case Complaint #3). The date of illness onset was 18 December 2021. Samples collected by the Texas Department of State Health Services do not test positive for *Cronobacter*. This is the second case with a clinical isolate sample available for comparison to environmental samples that will be taken during FDA’s inspection later this month at the Sturgis facility.
- **27 January 2022** – FDA contacts Abbott Nutrition to announce our intention to proceed with an inspection. Abbott Nutrition informs FDA of a continued COVID-19 outbreak among its employees.
- **31 January – 18 March 2022** – FDA proceeds with an inspection of Sturgis plant despite the COVID-19 outbreak given the fact pattern indicating a potential issue. FDA finds significant, fundamental sanitation, building, and equipment issues and takes multiple environmental samples.²
- **7 February 2022** – Seven of FDA’s environmental swabs suggest the potential presence of *Cronobacter*, but require confirmatory testing.
- **9 February 2022** – FDA leadership informed of potential positive samples, defined as “Cannot Rule Out” (unconfirmed) taken during the inspection of Abbott Nutrition’s Sturgis plant.
- **10 February 2022** – Food Program Leadership meets, and FDA’s Coordinated Outbreak Response Network begins coordinating a response.
- **11 February 2022** – FDA notifies USDA’s WIC program of potential action that could impact the infant formula supply.
- **13 February 2022** – FDA sequences six confirmed samples of *Cronobacter* collected from Abbott Nutrition’s Sturgis facility environment during the recent inspection. Nineteen additional samples are being sequenced.
- **14 February 2022** – An FDA intra-agency group, including experts and leadership from OFPR and CFSAN, begins discussions of food safety, regulatory, and supply chain issues related to the response. FDA updates USDA WIC on the investigation status.
- **15 February 2022** – FDA recommends Abbott Nutrition voluntarily recall product. FDA receives additional *Cronobacter* sample results, meets with USDA WIC on the investigation, potential for a recall, and supply chain issues. Abbott Nutrition voluntarily ceases production. FDA seeks, and Abbott Nutrition agrees to, exclude and hold specialty metabolic products given the critical access need and Abbott Nutrition’s lack of a mitigation plan to produce these formulas at one of its other facilities.

² U.S. Food and Drug Administration, “Form 483: Inspectional Observations; Abbott Nutrition, Sturgis, Michigan Facility,” January 31-March 18, 2022, available at https://www.fda.gov/media/157073/download?utm_medium=email&utm_source=govdelivery.

- **16 February 2022** – FDA again recommends Abbott Nutrition voluntarily recall product. FDA, as a Co-Sector Risk Management Agency of the Food and Agriculture Sector, submits 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 begins discussion with Abbott Nutrition on additional testing for these held products and a strategy to release products to those in dire need. FDA meets with the American Academy of Pediatrics to make them aware of a significant upcoming action involving infant formula that will have ramifications for supply chains. We share that our communications would advise parents to consult with the child’s health care provider for advice, with additional communications forthcoming from FDA.
- **17 February 2022** – Following a third recommendation by FDA that Abbott Nutrition voluntarily recall product, FDA issues a consumer advisory warning consumers to avoid certain Abbott Nutrition products as Abbott Nutrition voluntarily recalls product. FDA begins regular reports and coordination with USG partners on supply chain. CDC notifies FDA of a fourth case that may be related. Daily situation reports begin for FDA staff and leadership working on the response. FDA requests from IRI infant formula in-stock rates at the national level, which was not previously tracked by FDA. FDA requests that FMI, the Food Industry Association (FMI) ask retailers to limit sales to no more than five cans per shopper; FMI recommends the limit to retailers later that day.
- **18 February 2022** – FDA receives a fourth *Cronobacter* case report of a death potentially associated with Abbott Nutrition product (Case Complaint #4). FDA contacts other infant formula manufacturers to discuss actions to address potential supply chain disruptions. The date of illness onset for this case was 4 January 2022. No clinical isolate is available, and product samples do not test positive for *Cronobacter*. FDA requests an independent expert conduct a batch review of held specialty metabolic product.
- **22 February 2022** – First infant formula data sets obtained by FDA from IRI.
- **24 February 2022** – Russia invades Ukraine. This leads to additional uncertainty in the infant formula supply chain as Ukraine is a major exporter of sunflower oil, an ingredient used in many infant formulas. Manufacturers begin to re-assess their supplies and make plans in consultation with FDA about possible substitutions.
- **28 February 2022** – Abbott Nutrition voluntarily expands its recall at FDA’s recommendation to cover additional products associated with the fourth case complaint.
- **Late February – early March 2022** – FDA meets with retailers and other infant formula manufacturers throughout this period on actions to address infant formula supply chain and to seek supply chain information. FDA continues regular coordination with manufacturers. FDA follows up on several additional *Cronobacter* complaints but eventually determines them unrelated to Abbott Nutrition. Actions ultimately result in significant increases in domestic production by late April and early May.
- **15 – 16 March 2022** – FDA inspection team returns to Sturgis facility to obtain additional records related to complaints received. FDA receives FY 2022 additional funding to hire four additional infant formula staff.
- **18 March 2022** – January 2022 inspection and related sampling activities conclude. Inspection is closed, and FDA issues its inspection observations (FDA Form 483).³ Observations from inspection and FDA’s lack of confidence in Abbott Nutrition’s food safety culture inform FDA’s decision to negotiate a consent decree with the goal of addressing these observations and safely resuming production at Sturgis as soon as possible.
- **28 March 2022** – FDA’s FY 2023 budget request includes infant formula and medical foods supply chain legislative proposal.

³ U.S. Food and Drug Administration, “Form 483: Inspectional Observations; Abbott Nutrition, Sturgis, Michigan Facility,” January 31-March 18, 2022, available at https://www.fda.gov/media/157073/download?utm_medium=email&utm_source=govdelivery.

- **31 March 2022** – Abbott Nutrition provides FDA the independent batch review of specialty metabolic product requested 18 February.
- **1 April 2022** – FDA transforms response activity to an Agency-wide Incident Management Group to manage the response, including supply chain.
- **20 April 2022** – FDA communicates to Abbott Nutrition our decision not to object to release of specialty metabolic product broadly after enhanced finished product testing, and not to object to release on case-by-case basis for urgent need. This was communicated to Abbott Nutrition again on 20 April and 28 April.
- **29 April 2022** – FDA issues an updated advisory to ensure consumers are aware of Abbott Nutrition’s process to release metabolic formulas on a case-by-case basis, in consultation with a healthcare provider, to those families who have no alternative supply.
- **16 May 2022** – FDA and Abbott Nutrition sign a proposed consent decree.
- **16 May 2022** – U.S. District Court for the Western District of Michigan enters the consent decree. FDA issues enforcement discretion guidance to provide flexibilities to boost the supply of infant formula.
- **20 May 2022** – FDA issues its first enforcement discretion letter for a specialty infant formula product. FDA is evaluating additional requests for enforcement discretion. FDA is working with USG partners to arrange air transport for amino acid and hypoallergenic hydrolyzed formulas to arrive in the United States on 22 May 2022.