

‘Timeline of Failure:’ The Biden Administration and U.S. Food and Drug Administration Failed Response to the Infant Formula Crisis

2019

- **September 16-24:** U.S. Food and Drug Administration (FDA) officials conduct an inspection of the Abbott Sturgis, Michigan infant formula plant, which produces the majority of amino acid infant formula in the United States. As an outcome, the plant receives a Voluntary Action Indicated (VAI) and a Form 483. The FDA does not issue any restrictions or obligations on manufacturing at the plant.¹

2020-2021

- **2020:** During the COVID-19 pandemic, the FDA transitions to conducting “mission critical” inspections. It does not re-inspect the Abbott Sturgis facility to follow up on the previously issued Form 483 and ensure appropriate actions have been taken. **The FDA will not inspect the Abbott Sturgis facility again for another two years.**

2021

- **January 20:** Joe Biden inaugurated as 46th President of the United States.
- **July:** Nationwide out of stock rate for infant formula is 8 percent.²
- **September 20-24:** FDA conducts first inspection of the Abbott Sturgis plant in two years. Inspectors find the issues uncovered in the 2019 surveillance inspection have been resolved, but issue a Voluntary Action Indicated (VAI) for different items and a Form 483 for formula inspection.³
- **September 20:** FDA receives the first complaint that a child was hospitalized with *cronobacter sakazakii* on September 6th in Minnesota. The complaint is received at the same time an FDA investigator is conducting the Abbott Sturgis plant’s routine surveillance inspection.
- **November:** Nationwide out of stock rate for infant formula rises to 11 percent.⁴
- **November 12:** Dr. Robert Califf nominated to serve as Commissioner of Food and Drugs, 10 months after President Biden assumed office.
- **December 1:** FDA receives a second complaint, related to the death of a child in Ohio. The Centers for Disease Control determines *cronobacter* “could have been a contributing factor” in the death.⁵

¹ <https://www.fda.gov/media/157319/download>.

² <https://www.cnn.com/2022/05/08/business/baby-formula-shortage/index.html>.

³ <https://www.fda.gov/media/157317/download>.

⁴ <https://www.usatoday.com/story/money/2022/05/13/baby-formula-shortage-price-gouge-cost/9750034002/?gnt-cfr=1>.

⁵ <https://foodpoisoningbulletin.com/2022/timeline-chronobacter-illnesses-linked-to-infant-formula/>.

<https://www.cdc.gov/cronobacter/outbreaks/infant-formula.html>.

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2022

- **January 11:** FDA receives a third complaint, related to a child hospitalized with cronobacter on January 4, 2022 in Texas.
- **January 13:** Dr. Califf’s nomination to serve as Commissioner of Food and Drugs is reported favorably out of the Senate Health, Education, Labor and Pensions Committee.⁶
- **January 28:** The *New York Times* reports baby formula shortages are “worsening throughout the United States, causing parents to be increasingly concerned about how they will feed their infants.”⁷
- **January 31:** FDA begins a delayed follow-up inspection of the Abbott Sturgis plant.
- **February 13:** Nationwide out of stock rate for infant formula rises to 26 percent.⁸
- **February 15:** Dr. Robert Califf is confirmed by U.S. Senate as new Commissioner of Food and Drugs.⁹
- **February 17: Abbott announces a voluntary recall and hold of certain powdered infant formulas produced at the Abbott Sturgis plant.¹⁰ The same day, the FDA receives a fourth complaint, related to the death of a child, also in Ohio, with cronobacter.**
- **February 28:** After learning of the latest complaint received by the FDA, Abbott expands their recall to include a specialty product from a specific lot linked to that complaint. The FDA fully agreed with the firm’s decision to initiate, and then expand, the recall. FDA issues a recall notice.¹¹
- **February: As Abbott takes voluntary actions that limit production, Biden Administration officials are aware of the growing infant formula problem.** When questioned by CNN, White House National Economic Council Director Brian Deese said, “As a parent, and with friends and colleagues, we were aware that people were starting to have trouble in stores, but we were aware of this from when the FDA had to take its action back in February, with Abbott and with the steps in the Michigan facility. And we have had a team on this from the FDA and in the interagency process since then.”¹²
- **March 18:** FDA concludes its delayed follow-up inspection of the Abbott Sturgis plant.

⁶ <https://www.help.senate.gov/chair/newsroom/press/help-committee-advances-fda-nominee-dr-califf-others>.

⁷ <https://www.nytimes.com/2022/01/28/well/family/baby-formula-shortage.html>.

⁸ <https://www.washingtonpost.com/business/2022/05/11/baby-formula-shortage-similac-alimentum-elecare-fda/>.

⁹ <https://www.reuters.com/world/us/us-senate-confirms-bidens-fda-nominee-califf-2022-02-15/> .

¹⁰ <https://www.similacrecall.com/us/en/home.html>.

¹¹ <https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-infections-powdered-infant-formula-february-2022>.

¹² <https://dailycaller.com/2022/05/13/brian-deese-biden-administration-knew-formula-shortage-february/>.

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- **March 20:** Nationwide out of stock rate for infant formula rises to 30 percent.¹³
- **March 22:** Abbott begins flying FDA-approved baby formula daily from Europe.¹⁴
- **March 24:** President Biden states there will be “real” food shortages related to Russia’s war on Ukraine.¹⁵
- **April 1:** FDA establishes an Incident Management Group (IMG) to work on supply chain and food safety issues.¹⁶
- **April 8:** Abbott submits response and corrective action plan following FDA’s 2022 inspection. Abbott immediately begins implementing protocol corrective actions and plant upgrades.¹⁷
- **April 28:** Politico reports a former Abbott employee filed a whistleblower complaint with the FDA about the Sturgis plant in October 2021, yet the FDA took no follow up action.¹⁸
- **April 29:** FDA announces it informed Abbott Nutrition that the Agency has no objection to the company immediately releasing recalled product to individuals needing urgent, life-sustaining supplies of specific specialty and metabolic formulas on a case-by-case basis.¹⁹
- **Late-April:** In 26 states, out of stock rate for infant formula rises to 40-50 percent.²⁰
- **May 1:** Nationwide out of stock rate for infant formula rises to 43 percent.²¹
- **May 10:** FDA announces steps to improve supply of infant and specialty formula products.²² FDA downplayed the shortage, reporting that despite less available variety, 13% more total volume of infant formula was sold in April than was sold in March.²³

¹³<https://www.washingtonpost.com/business/2022/05/11/baby-formula-shortage-similac-alimentum-elecare-fda/>.

¹⁴ <https://www.abbott.com/corpnnewsroom/nutrition-health-and-wellness/abbott-update-on-powder-formula-recall.html>.

¹⁵ <https://www.bloomberg.com/news/articles/2022-03-24/biden-says-to-expect-real-food-shortages-due-to-ukraine-war>.

¹⁶ <https://spectrumlocalnews.com/tx/dallas-fort-worth/news/2022/05/13/cdc-closes-contamination-recall--but-baby-formula-recall-still-in-effect>.

¹⁷ <https://abbott.mediaroom.com/2022-05-16-Abbott-Enters-into-Consent-Decree-with-U-S-Food-and-Drug-Administration-for-its-Sturgis,-Mich,-Plant-Agreement-Creates-Pathway-to-Reopen-Facility>.

¹⁸ <https://www.politico.com/news/2022/04/28/whistleblower-fda-baby-formula-00028569>.

¹⁹ <https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-infections-powdered-infant-formula-february-2022>.

²⁰ <https://www.cbsnews.com/news/baby-formula-shortage-rationing-national-crisis/>.

²¹ <https://www.washingtonpost.com/business/2022/05/11/baby-formula-shortage-similac-alimentum-elecare-fda/>.

²² <https://www.fda.gov/news-events/press-announcements/fda-takes-important-steps-improve-supply-infant-and-specialty-formula-products>.

²³ <https://www.fda.gov/news-events/press-announcements/fda-provides-new-updates-activities-mitigate-infant-formula-supply-challenges-abbott-nutrition>.

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- **May 13:** USDA announces flexibilities, including implementing a number of waivers, urging states to permit alternative formulas for beneficiaries, and ease customer purchasing requirements.²⁴
- **May 14:** The Centers for Disease Control and Prevention (CDC) announces it has closed its investigation into the Abbott Sturgis facility, as no additional cases have been reported. The agency concluded there were no strains of cronobacter in sealed infant formula containers. The strains collected from the affected children did not match any strains present at Abbott facilities; they did match strains found in the childrens’ home environments.²⁵
- **May 16:** FDA and Abbott announce they have entered into a proposed consent decree, subject to court approval and entry, with a plan for reopening the Sturgis plant.²⁶ FDA also announces increased flexibilities to encourage importation of safe infant formulas into the United States.²⁷
- **May 18:** The Biden administration initiates “Operation Fly Formula,” modeled on the Trump administration’s successful COVID response framework known as “Project Air Bridge.”²⁸ President Biden invokes the Defense Production Act to require manufacturers of ingredients used in formula to prioritize orders placed by formula producers over others.²⁹
- **May 19:** Dr. Califf testifies the Abbott Sturgis plant will take another one to two weeks to reopen, after the plant has been closed for nearly four months.³⁰ Once the plant is reopened, officials estimate it will take another eight weeks to restock shelves with infant formula.³¹

²⁴ <https://www.usda.gov/media/press-releases/2022/05/13/usda-continues-urgent-actions-address-infant-formula-shortage>.

²⁵ <https://www.cdc.gov/cronobacter/outbreaks/infant-formula.html>.

²⁶ <https://abbott.mediaroom.com/2022-05-16-Abbott-Enters-into-Consent-Decree-with-U-S-Food-and-Drug-Administration-for-its-Sturgis,-Mich,-Plant-Agreement-Creates-Pathway-to-Reopen-Facility>. <https://www.fda.gov/news-events/press-announcements/fda-provides-new-updates-activities-mitigate-infant-formula-supply-challenges-abbott-nutrition>.

²⁷ <https://www.fda.gov/news-events/press-announcements/fda-encourages-importation-safe-infant-formula-and-other-flexibilities-further-increase-availability>.

²⁸ <https://www.whitehouse.gov/briefing-room/statements-releases/2022/05/18/fact-sheet-president-biden-announces-new-actions-to-address-infant-formula-shortage/>.

²⁹ <https://www.forbes.com/sites/zacharysmith/2022/05/18/biden-invokes-defense-production-act-to-require-manufacture-of-baby-formula-ingredients/?sh=38646b6e43a0>.

³⁰ <https://www.reuters.com/business/retail-consumer/abbott-baby-formula-plant-track-reopen-within-1-2-weeks-fda-commissioner-2022-05-19/>.

³¹ <https://www.washingtonpost.com/business/2022/05/14/baby-formula-shortage-sturgis/>.