

FDA concedes delays in response to baby formula shortage

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Similac Alimentum Hypoallergenic Infant Formula, imported from Puerto Rico, is for sale at a Stew Leonard's grocery store in Yonkers, New York, Friday, June 10, 2022. The FDA acknowledged Tuesday, Sept. 20, that its response to the national shortage of infant formula was slowed by delays in processing a whistleblower complaint and test samples from the nation's largest manufacturing plant. A 10-page report from the agency offers the first formal account of the factors that led to the ongoing infant formula shortage. Credit: AP Photo/Ted Shaffrey, File

The Food and Drug Administration acknowledged Tuesday that its response to the U.S. [infant formula shortage](#) was slowed by delays in processing a whistleblower complaint and test samples from the nation's largest formula factory.

A 10-page report from the agency offers its first formal account of the factors that led to the ongoing shortage, which has forced the U.S. to airlift millions of pounds of [powdered formula from overseas](#).

The review zeroed in on several key problems at the agency, including outdated data-sharing systems, inadequate staffing and training among its food inspectors, and poor visibility into [formula](#) supply chains and manufacturing procedures.

"For things that are critical to the public health, if you don't have some understanding of how all the pieces fit together, then when you get into a crisis or a shortage you have a real problem," FDA Commissioner Robert Califf told The Associated Press in an interview. "To a large extent that's what happened here."

Califf said the FDA will seek new authority to compel companies to turn over key information.

One consumer advocate said the evaluation doesn't go far enough to fix the problems.

"This internal evaluation treats the symptoms of the disease rather than offering a cure," Scott Faber of the Environmental Working Group said in a statement. "Nothing in this evaluation addresses the fragmented leadership structure that led to critical communication failures."

The FDA report was overseen by a senior official who interviewed dozens of agency staffers. It comes nearly eight months after the FDA shuttered Abbott's Michigan plant due to safety concerns, quickly slashing domestic production within the highly concentrated formula industry.

A company whistleblower had tried to warn the FDA of problems at the plant in September 2021, but government inspectors didn't investigate the complaints until February after four infants became sick, resulting in two deaths. The FDA is still investigating links between those illnesses and the formula.

The FDA previously [told Congress](#) that top agency officials didn't learn about the complaint until February because of mail delays and a failure to escalate the Abbott employee's allegations. The new report stated that FDA's "inadequate processes and lack of clarity related to whistleblower complaints," may have delayed getting inspectors to the plant.

"Whistleblower complaints come into the agency in many different ways, from many different sources," said Dr. Steven Solomon, an FDA veterinary medicine official who oversaw the review. "One of the actions we've already taken is to make sure that however they come into the agency, they get triaged and escalated to the right leadership levels."



Shelves typically stocked with baby formula sit mostly empty at a store in San Antonio, Tuesday, May 10, 2022. The FDA acknowledged Tuesday, Sept. 20, that its response to the national shortage of infant formula was slowed by delays in processing a whistleblower complaint and test samples from the nation's largest manufacturing plant. A 10-page report from the agency offers the first formal account of the factors that led to the ongoing infant formula shortage. Credit: AP Photo/Eric Gay, File

FDA inspectors collected bacterial samples from the plant for testing, but shipping issues by "third party delivery companies" delayed the results, according to the report. The FDA also faced challenges ramping up its testing capacity for *Cronobacter*, a rare but potentially deadly bacteria repeatedly linked to outbreaks in baby formula.

The FDA also noted that it had to reschedule its initial inspection of the Abbott plant due to cases of COVID-19 among company staff. That delay came on top of earlier missed inspections because the agency [pulled its inspectors](#) from the field during the pandemic.

The report concluded by listing new resources that Congress would need to authorize to improve infant formula inspections and standards, including:

- Increased funding and hiring authority to recruit experts to FDA's food division;
- Improved information technology to share data on FDA inspections, consumer complaints and testing results;
- New authority to compel manufacturers to turn over samples and records on manufacturing supply chains, manufacturing quality and safety.

U.S. inventories of baby formula have been improving, hitting in-stock rates above 80% last week, according to IRI, a market research firm. That's up from a low of 69% in mid-July. The U.S. has imported the equivalent of more than 80 million bottles of formula since May, according to White House figures, and the Biden administration is working to help foreign manufacturers stay on the market long term to diversify supply.

Califf has commissioned a separate external review of FDA's food division citing "fundamental questions about the structure, function, funding and leadership" of the program. That review is being led by former FDA commissioner Dr. Jane Henney, who led the agency during the final years of the Clinton administration.

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