

US reaches deal to reopen shuttered baby formula plant

May 17 2022, by Zeke Miller and Matthew Perrone



President Joe Biden speaks in the Rose Garden of the White House in Washington, Friday, May 13, 2022, during an event to highlight state and local leaders who are investing American Rescue Plan funding. Credit: AP Photo/Andrew Harnik

U.S. officials on Monday reached an agreement to allow baby formula

maker Abbott to restart its largest domestic factory, though it will be two months or more before any new products ship from the site to help alleviate the [national shortage](#) facing parents.

Under the agreement, Abbott must work with outside experts to upgrade its standards and reduce [bacterial contamination](#) at the Sturgis, Michigan, facility, which the Food and Drug Administration has been investigating since early this year. The deal, which must be reviewed by a [federal judge](#), amounts to a legally binding agreement between the FDA and the [company](#) on steps needed to reopen the factory.

The agreement was filed in court by the U.S. Department of Justice, on behalf of the FDA.

After production resumes, Abbott said it will take eight to ten weeks before new products begin arriving in stores. The company didn't set a timeline to restart manufacturing, which must be cleared with the FDA.

The FDA is expected to announce additional steps Monday evening to allow more foreign imports into the U.S. to address the [supply problems](#). It comes as the administration of President Joe Biden faces intense pressure to do more to ease the shortage that has left many parents hunting for formula online or at [food banks](#).



Infant formula is stacked on a table during a baby formula drive to help with the shortage Saturday, May 14, 2022, in Houston. Parents seeking baby formula are running into bare supermarket and pharmacy shelves in part because of ongoing supply disruptions and a recent safety recall. Credit: AP Photo/David J. Phillip

Abbott's plant came under scrutiny in January when the FDA began investigating four bacterial infections among infants who consumed powdered formula from the plant. Two of the babies died.

In February, the company [halted production and recalled several brands](#) of powdered formula, squeezing supplies that had already been tightened by supply chain disruptions and stockpiling during COVID-19. The shortage has led retailers like CVS and Walgreen's to limit how many containers customers can purchase per visit.

Outrage over the issue has quickly snowballed and handed Republicans a fresh talking point to use against Biden ahead of November's [midterm elections](#).

Abbott is one of just four companies that produce roughly 90% of U.S. formula, and its brands account for nearly half that market.

After a six-week inspection, FDA investigators published a list of problems in March, including lax safety and sanitary standards and a history of bacterial contamination in several parts of the plant.



Katherine Gibson-Haynes helps distribute infant formula during a baby formula drive Saturday, May 14, 2022, in Houston. Parents seeking baby formula are running into bare supermarket and pharmacy shelves in part because of ongoing supply disruptions and a recent safety recall. Credit: AP Photo/David J. Phillip

Chicago-based Abbott has emphasized that its products have not been directly linked to the bacterial infections in children. Samples of the bacteria found at its plant did not match the strains collected from the babies by federal investigators. The company has repeatedly stated it is ready to resume manufacturing, pending an FDA decision.

Former FDA officials say fixing the type of problems uncovered at Abbott's plant takes time, and infant formula facilities receive more scrutiny than other food facilities. Companies need to exhaustively clean the facility and equipment, retrain staff, repeatedly test and document there is no contamination.

On Monday, FDA Commissioner Robert Califf told ABC News that an announcement was forthcoming about importing baby formula from abroad. The key issue is making sure the instructions for the formula are in languages that mothers and caregivers can understand, he noted.

Pediatricians say baby formulas produced in Canada and Europe are roughly equivalent to those in the U.S. But traditionally, 98% of the infant formula supply in the U.S. is made domestically. Companies seeking to enter the U.S. face several major hurdles, including rigorous research and manufacturing standards imposed by the FDA.

San Diego father Steven Hyde has faced heart-wrenching challenges finding formula for his medical fragile daughter, who was on an Abbott [formula](#) but has had to switch with the recall and subsequent shortages in other brands.



People wait in line during a baby formula drive to help with the baby formula shortage Saturday, May 14, 2022, in Houston. Parents seeking baby formula are running into bare supermarket and pharmacy shelves in part because of ongoing supply disruptions and a recent safety recall. Credit: AP Photo/David J. Phillip

Zoie Hyde was born 19 months ago with no kidneys, a rare life-threatening condition that requires dialysis and a [feeding tube](#) until she weighs enough for a [kidney transplant](#).

Hyde said he used an organic brand from overseas until costs and customs hurdles made that too difficult. Friends and strangers from out of state have sent him other brands, but each time she switches requires more blood tests and monitoring, Davis said.

Despite her challenges, Zoie is walking, talking and "doing pretty good" on other developmental milestones, Davis said.

"She's a shining light in my life," he said.

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Citation: US reaches deal to reopen shuttered baby formula plant (2022, May 17) retrieved 27 April 2024 from <https://medicalxpress.com/news/2022-05-reopen-shuttered-baby-formula.html>

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