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THE UNITED STATES

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Monday, May 16, 2022

Justice Department Files Complaint and Proposed Consent Decree to Ensure Safety of Abbott Laboratories' Infant Formula

The United States has filed a complaint and a proposed consent decree that, if entered by a federal court in the Western District of Michigan, would allow Abbott Laboratories (Abbott) to resume manufacturing powdered infant formula at its Sturgis, Michigan, facility but also would require the company to take specific measures designed to increase safety and ensure compliance with the Federal Food, Drug, and Cosmetic Act (FDCA) and the U.S. Food and Drug Administration's (FDA) Good Manufacturing Practice Requirements.

"The actions we are announcing today will help to safely increase the supply of baby formula for families," said Attorney General Merrick B. Garland. "The Justice Department will vigorously enforce the laws ensuring the safety of our food and other essential consumer products, and we will work alongside our partners across government to help make sure those products are available to the American people."

In a complaint filed May 16, the United States alleged that Abbott, Division Vice-President of Quality Assurance Lori J. Randall, Sturgis Director of Quality Keenan S. Gale, and Sturgis Site Director TJ Hathaway manufactured powdered infant formula under conditions and using practices that failed to comply with regulations designed to ensure the quality and safety of infant formula, including protection against the risk of contamination from bacteria such as *Cronobacter sakazakii*. The *Cronobacter sakazakii* bacteria can live in dry foods, such as powdered infant formulas, and can cause deadly sepsis or meningitis in infants. The complaint further alleged that FDA testing of environmental samples taken in February detected *Cronobacter sakazakii* in the defendants' manufacturing facility.

Abbott has agreed to resolve the complaint in a proposed consent decree of permanent injunction. Under the proposed consent decree, which must still be reviewed and entered by a federal court, Abbott must retain outside expert assistance to bring its facility into compliance with the FDCA and good manufacturing practice regulations. Among other things, the expert will assist Abbott, under FDA supervision, in the development of plans designed to reduce and control the risk of bacterial contamination, and will periodically evaluate Abbott's compliance with the FDCA, regulations, and the consent decree. The proposed consent decree also follows a thorough FDA inspection of the Sturgis facility and ongoing efforts by Abbott to address observations made during that inspection. The proposed consent decree sets out what Abbott must do to resume safely manufacturing infant formula at the Sturgis facility, which will help to mitigate the shortage of infant formula while also protecting public health.

"Federal laws regarding the safe manufacture of food, particularly food for infants, must be rigorously enforced," said Principal Deputy Assistant Attorney General Brian Boynton, head of the Justice Department's Civil Division. "The proposed consent decree underscores the Department's commitment to protecting our most vulnerable citizens while also ensuring access to an essential product."

"Parents who feed their babies formula must have confidence these products are safe," said U.S. Attorney Mark Totten for the Western District of Michigan. "This proposed consent decree aims to protect one of our most vulnerable populations. My office is fully committed to supporting FDA and working with its partners at the Consumer Protection Branch to ensure manufacturers in our district comply with FDA's safety regulations."

"Today's action means that Abbott Nutrition has agreed to address certain issues that the agency identified at their infant formula production facility in Michigan," said FDA Commissioner Robert M. Califf, M.D. "The public should rest assured that the agency will do everything possible to continue ensuring that infant and other specialty formulas produced by the company meet the FDA's safety and quality standards, which American consumers have come to expect and deserve. We recognize the hardships that parents and caregivers have faced in obtaining infant formula and the FDA is focused on boosting the availability of the country's supply of these products, including new steps regarding importation. We are also taking a look at the supply of infant formulas developed by manufacturers across the country and around the world to determine if a reallocation of their distribution can be made to help get the right product to the right place, at the right time."

This proposed consent decree is part of the Department's broader work to address the current infant formula shortage. As part of these efforts, Associate Attorney General Vanita Gupta sent a letter to state attorneys general today, urging them to use their state-law authorities to ensure that vulnerable families are not taken advantage of during this time, and encouraging them to contact the Department with any evidence of collusive price fixing, bid rigging, or market allocation. The Associate Attorney General's letter can be found here:

<https://www.justice.gov/asg/page/file/1506016/download>.

This matter is being handled by Senior Litigation Counsels Donald R. Lorenzen and Christina Parascandola of the Civil Division's Consumer Protection Branch and Assistant U.S. Attorney Andrew Hull for the Western District of Michigan, with the assistance of Senior Counsel Claudia Zuckerman of the FDA's Office of the Chief Counsel.

Additional information about the Consumer Protection Branch and its enforcement efforts may be found at <http://www.justice.gov/civil/consumer-protection-branch>. For more information about the U.S. Attorney's Office for the Western District of Michigan, visit its website at <https://www.justice.gov/usao-wdmi>.

Attachment(s):

[Download Abbott Proposed Consent Decree.pdf](#)

[Download Abbott Complaint.pdf](#)

Topic(s):

Consumer Protection

Component(s):

[Civil Division](#)

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