United States Senate
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS
WASHINGTON, DC 20510–6300

December 18, 2025

VIA ELECTRONIC TRANSMISSION

Ron Belldegrun
Chief Executive Officer and Co-Founder
ByHeart
131 Varrick Street, 11th Floor
New York, NY 10013

Mia Funt
President and Co-Founder
ByHeart
131 Varrick Street, 11th Floor
New York, NY 10013

Dear Mr. Belldegrun and Ms. Funt,

Ensuring that parents and their infants have access to safe formula is essential for us to protect our most vulnerable population. There should never be any question about the quality of these products. The ongoing safety recall affecting ByHeart products undermines access to safe, quality infant formula by putting pressure on the overall supply of infant formula.

On November 8, the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) recommended that ByHeart conduct a voluntary recall due to an outbreak of infant botulism "among infants consuming ByHeart powdered infant formula."[1] While FDA and CDC continue to investigate the outbreak, a total of 51 infants who consumed ByHeart products across 19 states have been identified with suspected or confirmed infant botulism .[2]

As Chairman of the Senate Committee on Health, Education, Labor, and Pensions (HELP), I am concerned about the release of inspection reports finding that ByHeart facilities had numerous safety deficiencies, including failing to take steps to limit contamination or adulteration of product manufactured in those facilities.[3] It is important for the public to not only understand how infants were infected with botulism, but to determine what steps should be taken to strengthen protections and to ensure the safety of infant formula. To that end, I request answers to the following questions, on a **question-by-question basis**, by **January 14, 2025**.

[1] *Outbreak Investigation of Infant Botulism: Infant Formula (November 2025)*, U.S. Food and Drug Administration (Dec. 10, 2025), https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-infant-botulism-infant-formula-november-2025?utm_medium=email&utm_source=govdelivery.
[2] *Id*.
[3] *Inspection Report – Blendhouse Allterton, LLC*, U.S. Food and Drug Administration (Feb. 20, 2025), https://www.fda.gov/media/189923/download.

1. When did ByHeart first become aware of safety concerns regarding its infant formula?

2. How is ByHeart engaging with retailers to ensure that any recalled infant formula batches are no longer being sold?

3. How is ByHeart engaging with state and federal entities to limit any supply chain impact associated with ByHeart's safety recall?

4. What safety processes, including testing frameworks, does ByHeart have in place to ensure infant formula products are safe?
   a. Does ByHeart work with any third-party entities to review and improve safety processes?
   b. Does ByHeart conduct any proactive inspection of its facilities?
   c. In the last five years, has ByHeart identified any safety hazards at its facilities in Allerton, IA, Portland, OR, or Reading, PA. If so, please provide a list of any identified hazards and steps ByHeart took to address those.

5. FDA recently released records for inspections conducted between 2022 and March 2025 finding non-compliance with requirements for good manufacturing practices (GMPs), including "Not maintaining a building used in the manufacture, processing, packing or holding of infant formula in a clean and sanitary condition."[4]
   a. Between 2022 and March 2025, how many GMP deficiencies did FDA note as part of their inspections? Please provide a list of each identified deficiency.
   b. For each identified deficiency, please provide a list of how ByHeart resolved those deficiencies.

6. Has ByHeart voluntarily removed any infant formula batches manufactured in the United States sold in foreign markets?
   a. Has ByHeart received any engagement regarding safety with foreign product regulators?

Sincerely,

Bill Cassidy, M.D.

Bill Cassidy, M.D.
Chairman
U.S. Senate Committee on Health,
Education, Labor, and Pensions

[4] *Id.*