TAXPAYERS PROTECTION ALLIANCE

May 11, 2022

Susan T. Mayne Ph.D.
Director, Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Building CPKI, Room 4B064
College Park, MD 20740

Dear Dr. Mayne,

On behalf of millions of taxpayers and consumers across the country, the Taxpayers Protection Alliance (TPA) seeks clarification on the Food and Drug Administration's (FDA) regulatory policies regarding baby formula. As agency officials are well aware, the U.S. is currently experiencing a significant baby formula shortage. Data from the retail analysis firm Datasembly shows that the amount of baby formula available on supermarket and convenience store shelves is down approximately 40 percent from typical inventory levels.

A large majority of households with young children will feed their infants formula at least once by the time they are six months old. Continued shortages will have dire ramifications for child nutrition. Mothers receiving assistance from the federal Special Supplemental Nutrition Program for Women, Infants and Children will be particularly hard-hit because the program limits options to just a few supply-constrained formula brands.

Given these issues, and the FDA's extensive role in regulating the supply chain of baby formula, TPA has the following questions and concerns for the agency:

- Numerous media outlets have reported that Abbott Nutrition's February recall of baby formula is a key contributor to current shortage issues. The recalls were a direct result of FDA findings linking the formula to multiple infant illnesses and deaths. Abbott's formula was found to contain the bacteria Cronobacter sakazakii, which can cause serious health issues if ingested.

  According to a 2015 research article published in the journal *Applied and Environmental Microbiology*, an economical phage purification and concentration method could successfully control Cronobacter sakazakii in infant formula and mitigate contamination and harm.[1] Yet, regulatory application and approval of phage biocontrol products appear to be relatively limited. According to one estimate published in 2021 in *Current Issues in Molecular Biology*, eleven such biocontrol products have been approved under the Generally Recognized as Safe (GRAS)

[1] Lee, Ju-Hoon, Jaewoo Bai, Hakdong Shin, Yeran Kim, Bookyung Park, Sunggi Heu, and Sangryeol Ryu. "A novel bacteriophage targeting Cronobacter sakazakii is a potential biocontrol agent in foods." *Applied and Environmental Microbiology* 82, no. 1 (2016): 192-201.

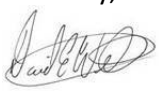
framework.[2] Seemingly, none have been approved for the specific treatment of C. sakazakii in baby formula. **TPA would like to know the rationale for this lack of regulatory approval. In the FDA's estimation, is this due to regulatory hurdles, corporate reluctance to embrace phage biocontrol products, or both?**

- In 2021, formula manufacturer Able Groupe announced the recall of 76,000 units of baby formula produced in Europe and distributed to U.S. consumers. The recall came as a result of the FDA's findings that, "the required pre-market notifications for these new infant formulas have not been submitted to the FDA" and the formulas "do not bear mandatory labeling statements in English."[3] While lack of labeling and pre-market communication with regulators could result in harms to U.S. consumers, the products targeted for FDA scrutiny are already under the purview of European regulators. Furthermore, purchases of these products would presumably not fall under agency scrutiny if parents either bought these products themselves abroad or had friends or relatives procure them abroad.

  Given the extraordinary challenges facing parents due to the formula shortage, it seems that the FDA could feasibly relax import restrictions on popular European baby formulas such as Holle, HiPP, and Lebenswert. Has the FDA examined European data regarding the safety of these brands before targeting foreign formulas for enforcement?

TPA recognizes that the FDA has a broad mandate to protect U.S. consumers and maintain product safety and integrity. However, there are credible concerns that these actions are too onerous and result in unintended consequences (i.e., formula shortages) that harm the well-being of infants and their families. We look forward to your responses and urge you to embrace regulatory transparency and flexibility.

Sincerely,



David Williams
President

[2] Vikram, Amit, Joelle Woolston, and Alexander Sulakvelidze. "Phage biocontrol applications in food production and processing." *Current Issues in Molecular Biology* 40, no. 1 (2021): 267-302.
[3] U.S. Food and Drug Administration. "Able Groupe Recalling Products Labeled as Infant Formula Formulas Have Insufficient Iron Levels as Per Requirements for Infant Formula in The U.S., and Products Do Not Meet Other FDA Requirements." Aug. 8, 2021.