WILMERHALE

Alyssa DaCunha

+1 202 663 6454 (t)
+1 202 663 6363 (f)
alyssa.dacunha@wilmerhale.com

July 11, 2022

By Electronic Mail

The Honorable H. Morgan Griffith, Ranking Member
Subcommittee on Oversight and Investigations
House Committee on Energy & Commerce
United States House of Representatives
2322 Rayburn House Office Building
Washington, D.C. 20515-4329

Dear Ranking Member Griffith:

I write on behalf of Gerber Products Company ("Gerber") in response to your letter dated June 24, 2022. Enclosed please find responses to your questions for the record from the Committee's May 25, 2022 hearing entitled "Formula Safety and Supply: Protecting the Health of America's Babies." We appreciate the opportunity to respond to your inquiry and provide information about Gerber's efforts to address the current infant formula shortage in the United States.

Best regards,

Alyssa DaCunha

Enclosure

cc: Hon. Frank Pallone, Jr.
Hon. Cathy McMorris Rodgers
Hon. Diana DeGette

1. **The CDC notes that *Cronobacter* is a germ that is naturally in the environment. Is it common for your company to detect *Cronobacter* in its manufacturing facilities?**

    a. **If so, what actions do your facilities take when it detects *Cronobacter* or other bacterium?**

    b. **Based on Gerber's understanding, can an infant formula manufacturing plant be in compliance with FDA requirements while occasionally finding environmental samples with *Cronobacter*? Why or why not?**

        i. **Has Gerber's infant manufacturing facilities ever detected *Cronobacter*, but remained compliant with FDA requirements and been allowed to stay open? If so, please explain.**

At Gerber, the quality and safety of our products, and the health and well-being of infants and young children, have always been our top priorities. Gerber has strict safety, quality, and compliance standards, many of which exceed U.S. Food and Drug Administration ("FDA") requirements. We implement current good manufacturing practices, including stringent procedures and controls at all levels of production, from the sourcing of raw materials and ingredients to the processing and distribution of our products. This includes thorough quality checks and rigorous testing at each of our food and formula facilities. Specifically, our infant formulas undergo as many as 500 quality and safety checks, and every finished batch of infant formula is tested for the presence of bacteria.

Cronobacter exists in the environment and occasionally, we identify cronobacter in our facilities. However, through our system of stringent process controls we minimize its presence in our manufacturing facilities and, most importantly, take steps to prevent it from reaching our products. Gerber tests every batch of infant formula before releasing it to the market, and we would never knowingly release any contaminated product.

2. **Please describe the type of routine testing that Gerber conducts at its manufacturing facilities, including what Gerber is testing for and how often the testing is conducted.**

    a. **What is Gerber's process for addressing any adverse findings during its routine testing? For example, who is notified of the adverse findings, is there paperwork that is created to document the adverse findings, are there corrective action plans put in place to address the adverse findings?**

    b. **If paperwork is created as a result of any adverse findings, does that paperwork come to your attention?**

For information on Gerber's rigorous testing protocols, please see the response to question 1.

In addition to routine testing and controls required by FDA, Nestlé has a global quality management program that governs how Gerber controls and addresses various microbiological organisms. For cronobacter, if an area in the facility has a positive environmental test result, the area is immediately cleaned and retested. Positive results found in designated areas/locations require an investigation to determine root cause and identify any corrective actions needed, including a heightened protocol for testing the environment and finished product. Gerber's system also includes an escalation process for results identified in those areas, including a review and evaluation of the corrective actions by our Global Team.

3. Has Gerber submitted requests to the FDA for the agency to review infant formula that is manufactured abroad but could be imported into the U.S.?

a. If so, please explain what those requests were, when they were made, and if and when FDA responded to those requests.

We welcome efforts by the FDA to give companies temporary flexibility with regard to the import of certain infant formulas. We are pleased to report that we have received enforcement discretion for all five requests we submitted under the new FDA guidance. The chart below summarizes these requests for the importation of Nestlé infant formula produced in our facilities abroad.

Product	**Country**	**Estimated cans of infant formula**	**Estimated full-size 8 oz bottles of infant formula**	**Nestlé request to FDA**	**FDA enforcement discretion received**
Nestlé® NAN® Supreme Pro 1 Nestlé® NAN® Supreme Pro 2	Germany	249,500	6.5 million	May 20, 2022 (NAN 1) May 25 (NAN 2)	June 1, 2022
Gerber® Good Start® Gentle	Mexico	1.3 million	33 million	May 23, 2022	June 3, 2022
Nestlé® NAN® Expert Pro SensiPro	Germany	28,200	745,000	May 31, 2022	June 9, 2022
Vitaflo PKU start™	Netherlands	3,192	43,671	June 10, 2022	July 6, 2022

Under this regulatory flexibility, we anticipate bringing in the equivalent of more than 40 million 8-ounce bottles of formula between June and October 2022. We will continue to review the new guidance and assess additional opportunities to tap into Nestlé's global nutrition network to help.

4. **Your written testimony noted that Gerber submitted its first request for enforcement discretion to import Nestle NAN Supreme Pro Stage 1, which Nestle produces in Germany for the Australian market and it is preparing a second submission that will allow them to import a larger size of its Gerber Good Start Gentle for WIC. When were those enforcement discretion applications submitted to FDA, and what is the status of those enforcement discretion applications?**

    a. **Has Gerber submitted additional enforcement discretion requests to FDA? If so, please specify what those requests were, when they were made, if FDA has approved those requests, and if they approved the request when the request was approved.**

These submissions are covered above in the response to question 3.

5. **It is my understanding that Gerber has been freighting additional infant formula product from overseas since before Project Fly Formula began. When did Gerber start air freighting over infant formula?**

    a. **How often were these shipments happening?**

Shortly after the Abbott recall was announced in February, Nestlé began accelerating import of specialty product produced at FDA registered factories outside the country to expedite availability in the market and serve immediate needs. This includes Gerber® Good Start® Extensive HA® from the Netherlands and Alfamino® from Switzerland for Nestlé Health Science as these products serve a critical medical purpose for children with cow's milk protein allergies. We accelerated the production of Gerber® Good Start® Extensive HA® formula, originally planned for later in the year, and rushed shipments via air freight. Also prior to Operation Fly Formula, our Nestlé Health Science team was producing four to six times the normal volume of its hypoallergenic amino acid-based formula Alfamino® and shipping the product via air from Switzerland.

We are proud to have been the first participant in the Administration's Operation Fly Formula, which has enabled us to expedite the import of critical specialty formula. We continue to work with the Administration to import infant formula, and through these efforts we expect to add more than 1.72 million cans of formula into the U.S. market supply for babies.

6. When did the federal government first start to implement waivers and flexibilities to allow for WIC consumers to purchase substitute infant formula products?

a. Are your companies communicating with the various state, territory, and tribal WIC agencies to help facilitate substitute products?

We share the commitment of the Special Supplemental Nutrition Program for Women, Infants, and Children ("WIC") to safeguard the health of low-income infants and children by providing nutritious and safe foods for infants, toddlers, and young children. And we support the U.S. Department of Agriculture offering states flexibility to help WIC participants access an alternative when the contract formula is not available.

Gerber is working closely and collaboratively with the six states and Puerto Rico where Gerber has contracted to provide rebated products through WIC to help ensure sufficient supply. While Gerber is a small manufacturer in this space, we are proud to serve our WIC states. Where possible, we are also working to assist other states that require support during this formula shortage.