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ONE HUNDRED SEVENTEENTH CONGRESS

# Congress of the United States

## House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

June 24, 2022

Mr. Robert Cleveland
Senior Vice President,
Nutrition, North America and Europe
Reckitt
225 North Canal Street, 25th Floor
Chicago, IL 60606

Dear Mr. Cleveland:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Wednesday, May 25, 2022, at the hearing entitled "Formula Safety and Supply: Protecting the Health of America's Babies." I appreciate the time and effort you gave as a witness before the Committee on Energy and Commerce.

Pursuant to Rule 3 of the Committee on Energy and Commerce, members are permitted to submit additional questions to the witnesses for their responses, which will be included in the hearing record. Attached are questions directed to you from a member of the Committee. In preparing your answers to these questions, please address your response to the member who has submitted the questions in the space provided.

To facilitate the printing of the hearing record, please submit your responses to these questions no later than the close of business on Monday, July 11, 2022. As previously noted, this transmittal letter and your responses, as well as the responses from the other witnesses appearing at the hearing, will all be included in the hearing record. Your written responses should be transmitted by e-mail in the Word document provided to Austin Flack, Junior Professional Staff, at austin.flack@mail.house.gov. To help in maintaining the proper format for hearing records, please use the document provided to complete your responses.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Austin Flack with the Committee staff at (202) 225-2927.

Sincerely,

Frank Pallone, Jr.
Chairman

Attachment

cc: The Honorable Cathy McMorris Rodgers
Ranking Member
Committee on Energy and Commerce

The Honorable Diana DeGette
Chair
Subcommittee on Oversight and Investigations

The Honorable H. Morgan Griffith
Ranking Member
Subcommittee on Oversight and Investigations

**Attachment—Additional Questions for the Record**

**Subcommittee on Oversight and Investigations**
**Hearing on**
**"Formula Safety and Supply: Protecting the Health of America's Babies"**
**May 25, 2022**

Mr. Robert Cleveland, Senior Vice President, Nutrition, North America and Europe, Reckitt

**The Honorable H. Morgan Griffith**

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

Answer

Cronobacter is a ubiquitous microorganism. At Reckitt, we have an aggressive environmental monitoring program designed to specifically test for Cronobacter, and annually each of our facilities takes thousands of swabs at various locations of our plants to ensure product safety. Our plant systems, controls and master sanitization program ensure that detection of Cronobacter at our plants is a very rare event.

In the event Cronobacter is detected, the site opens an investigation and develops a corrective action and preventative action plan to remediate. Effectiveness of the action plan is always verified by heightened swabbing, with the success criteria for this testing being zero repeat detections.

A plant can produce safely with extremely low levels of Cronobacter in the environment, and, at times, Cronobacter has been detected in the environment of our facilities at very low levels during our end-to-end microbiological testing programs. In these instances, the FDA has allowed our sites to continue to produce commercial product. All of our

plants test powdered infant formula at 600g for Cronobacter before release, which is twice the required testing amount under applicable regulations. Samples are taken from sixty cans of finished goods (representative of the entire batch) and from an autosampler that provides continuous sampling across the entire batch start to finish. To add further confidence, Reckitt sites apply state of the art HACCP and Quality Management System programs, which incorporate over 1800 requirements to ensure quality and food safety by design.

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

    a. **What is Reckitt'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?**

Answer

Reckitt plants apply broad ranging testing that includes foreign material and nutritional testing, in addition to rigorous microbiological testing. We apply this testing to incoming raw materials, to in-process intermediates, to semi-finished products and at the final finished goods stage. The manufacturing environment is subject to two tiers of microbiological testing. The first tier, or leading indicator, is testing of Enterobacteriaceae, which are hygiene indicators. The second tier, or lagging indicator, tests specifically for Cronobacter and Salmonella. These tests are monitored via KPI dashboards weekly. The same information is trended monthly and quarterly as part of the Supply and Quality Management review process.

Any adverse finding triggers an investigation and subsequently a corrective action and preventative action plan. All investigations and actions are documented as part of a site's quality management system. Site leadership is informed of the finding and action planning. Depending on the severity of the finding, regional and global Quality and Supply leadership may also participate in the review and actions planning.

Depending on the severity of the finding, I may be informed and briefed by the Quality and Supply head, who is part of my senior management team.

3. **Your testimony notes that Reckitt has been working closely with the FDA, including on ways to expedite review and approval of some of its infant formula manufactured at its facility in Mexico. When did Reckitt first submit the necessary materials to FDA for the agency's review?**

**a. Has Reckitt received a response from FDA on whether the infant formula manufactured at its facility in Mexico is cleared for distribution in the U.S.? If so, when did it receive that approval?**

**b. Has Reckitt submitted any other requests to FDA for expedited review of infant formula products manufactured at other facilities? If so, when were those submitted, and has Reckitt received a response from the FDA on those submissions?**

Answer

With respect to distribution of product manufactured abroad, our first priority was the submission of an Enforcement Discretion request for the importation of a base powder manufactured at our facility in Tuas, Singapore, for the production of infant formula in the U.S. This request was submitted on May 25, 2022 and approved by the FDA on June 15, 2022. We have since been assessing other opportunities for finished product and base powder options to be imported from our plant in Mexico. Recently, we have shifted our focus to the production of PurAmino amino-acid base powder in this facility. We expect to submit this Enforcement Discretion request to the FDA in the next few days.

**4. Has Reckitt 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. See above**

Answer

As explained on question # 3, our Enforcement Discretion request for the importation of base powder from Tuas, Singapore, was submitted on May 25, 2022 and approved by the FDA on June 15, 2022.

**5. 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?**

Answer

The USDA began allowing waivers for alternate brands and sizes of infant formula products in Abbott WIC states on February 20, 2022. On May 24, 2022, the Secretary of Agriculture took further action by notifying states that the USDA would

be paying the costs of any noncontract formula to be issued in Reckitt and Gerber WIC states.

We first worked with state WIC agencies to identify which alternate brands and sizes that we manufacture were most likely to be found on retail shelves in their states. We provided the state WIC agencies with information that included the monthly allotment they should issue to their WIC participants as well as rebate information for each of these items.

Additionally, as soon as the Secretary of Agriculture notified Reckitt and Gerber that the USDA would cover the cost of any noncontract formula in our WIC states, we immediately notified our WIC states and informed them that we were waiving any contract language that might limit their ability to issue noncontract formula brands to their WIC families. This action essentially allowed state WIC agencies to issue WIC benefits for any brand, form or size of their choosing, thereby providing state WIC agencies the maximum flexibility possible for their WIC families.