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ONE HUNDRED SEVENTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE

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June 10, 2022

The Honorable Robert M. Califf, M.D.
Commissioner
U.S Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Commissioner Califf,

We write to follow-up on our concerns about the ongoing nationwide infant formula shortage. During the Subcommittee on Oversight and Investigations May 25, 2022, hearing entitled “Formula Safety and Supply: Protecting The Health of America’s Babies,” Congressman Joyce asked you when the U.S. Food and Drug Administration (FDA) alerted the White House about the closure of Abbott’s plant in Sturgis, Michigan, and who at the White House was alerted.¹ In response, you stated that in “early February there were communications up and down the chain.”² Further, you stated that there were regular communications with White House staff.³ You also noted there are memos “that were produced that...give a very elegant description of the issues and the concerns.”⁴ In addition, the timeline of infant formula related activities provided as part of FDA’s testimony for the same hearing notes that on February 16, 2022, FDA submitted “a report to U.S. government (USG) partners on the potential recall and

¹ H. Comm. on Energy and Commerce Hearing, “Formula Safety and Supply: Protecting The Health of America’s Babies” (May 25, 2022), *available at* <https://energycommerce.house.gov/committee-activity/hearings/hearing-on-formula-safety-and-supply-protecting-the-health-of-america-s>.

² *Id.*

³ *Id.*; Testimony of Robert M. Califf, M.D., Frank Yiannas, M.P.H., and Susan T. Mayne, FDA, H. Comm. on Energy and Commerce Hearing, “Formula Safety and Supply: Protecting The Health of America’s Babies” (May 25, 2022), *available at* <https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/FDA%20Testimony%20ECOI%20Infant%20Formula%205.25.2022%20final.pdf>.

⁴ H. Comm. on Energy and Commerce Hearing, “Formula Safety and Supply: Protecting The Health of America’s Babies” (May 25, 2022), *available at* <https://energycommerce.house.gov/committee-activity/hearings/hearing-on-formula-safety-and-supply-protecting-the-health-of-america-s>.

supply chain impacts given the significant market share held by Abbott Nutrition, as well as the Sturgis facility being a critical producer of specialty metabolic and amino acid formulas.”⁵

However, during a White House roundtable on June 1, 2022, hosted by administration officials and infant formula manufacturers, President Biden stated that he was not briefed about the infant formula shortage and how intense it was until April 2022.⁶ Furthermore, U.S. Department of Commerce Secretary Gina Raimondo recently stated that she “probably” did not learn about the infant formula crisis until April, and that she is not “involved in the administration’s response.”⁷ Thus, it is important to understand how and when the infant formula issues were communicated and described by the FDA to the White House and other USG partners. To assist in a more fulsome examination of the administration’s response efforts, please produce the following to Committee staff by June 24, 2022:

1. A copy of each of the memos referenced in your May 25, 2022, oral testimony.
 - a. For each memo, please specify to whom the memo was produced and when the memo was produced to them.
2. A copy of the report referenced in FDA’s written testimony for the May 25, 2022, hearing.
 - a. Please specify to whom this report was sent and when the report was sent to them.
3. Besides the aforementioned memos and report, was there any other communication between the FDA and the White House regarding infant formula in February 2022?
 - a. If so, please specify the nature of this communication, including the dates, types of communication (i.e., meetings, emails, phone calls, video calls, etc.), FDA and White House personnel involved, and topics discussed.

⁵ Testimony of Robert M. Califf, M.D., Frank Yiannas, M.P.H., and Susan T. Mayne, FDA, H. Comm. on Energy and Commerce Hearing, “Formula Safety and Supply: Protecting The Health of America’s Babies” (May 25, 2022), *available at*

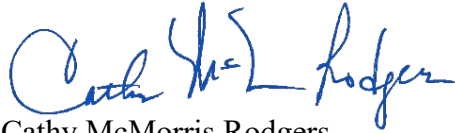
<https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/FDA%20Testimony%20ECOI%20Infant%20Formula%205.25.2022%20final.pdf>.

⁶ Remarks by President Biden During Virtual Meeting on Accelerating Infant Formula Production Through Operation Fly Formula, The White House (June 1, 2022), *available at* <https://www.whitehouse.gov/briefing-room/speeches-remarks/2022/06/01/remarks-by-president-biden-during-virtual-meeting-on-accelerating-infant-formula-production-through-operation-fly-formula/>.

⁷ Zach Schonfeld, *Commerce secretary says she ‘probably’ didn’t learn of baby formula shortage until April*, THE HILL (June 5, 2022), *available at* <https://thehill.com/news/sunday-talk-shows/3512328-commerce-secretary-says-she-probably-didnt-learn-of-baby-formula-shortage-until-april/>; Conn Carroll, *Who is in charge of Biden’s baby formula response?*, WASHINGTON EXAMINER (June 5, 2022), *available at* <https://www.washingtonexaminer.com/opinion/who-is-in-charge-of-bidens-baby-formula-response>.

If you have any questions, please contact Brittany Havens, Kristin Seum, and Alan Slobodin of the Minority Committee staff. Thank you for your attention to this request.

Sincerely,



Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce



H. Morgan Griffith
Republican Leader
Subcommittee on Oversight and
Investigations
Committee on Energy and Commerce



Brett Guthrie
Republican Leader
Subcommittee on Health
Committee on Energy and Commerce

CC: The Honorable Frank Pallone, Chairman
The Honorable Anna Eshoo, Chair, Subcommittee on Health
The Honorable Diana DeGette, Chair, Subcommittee on Oversight and Investigations