

Congress of the United States
House of Representatives

COMMITTEE ON OVERSIGHT AND ACCOUNTABILITY

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<https://oversight.house.gov>

March 21, 2023

Dr. Robert M. Califf
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Dr. Califf:

The Committee on Oversight and Accountability is continuing its investigation into the U.S. Food and Drug Administration's (FDA) response to the infant formula shortage and its restructuring of the food and nutrition division in response to the infant formula shortage.¹ The Reagan-Udall Foundation's report titled "Operational Evaluation of the FDA Human Foods Program," found that there was "little motivation, and no requirement," to "facilitate critical thinking and proactive decision-making" during the infant formula shortage.² Despite this report, and the acknowledged need for a major overhaul, you stated that there would be no reassignments nor firings over the administration's response to the infant formula shortage.³ We request documents and communications to understand the FDA's response to the infant formula shortage.

Formula shortages began in the summer of 2021 as global supply chains were disrupted by the COVID-19 pandemic.⁴ As the administration scrambled to contain the issue, families across the nation were presented with the question of how they would feed the infants in their families and communities. Now, instead of removing or reassigning the individuals at fault for the poor response to this crisis, the announced restructuring of the food and nutrition division simply requires certain offices and personnel to report to the newly created position of Deputy Commissioner for Human Foods.⁵ The Committee is concerned that the FDA's restructuring is a superficial attempt—rather than a real effort—to bring accountability and make meaningful changes.

To assist in our investigation of the FDA's response to the infant formula shortage, we request the following documents and information no later than April 4, 2023:

¹ Statement from Robert M. Califf, Comm'r of Food and Drugs, F.D.A., FDA Proposes Redesign of Human Foods Program to Enhance Coordinated Prevention and Response Activities (Jan. 31, 2023).

² *Id.*

³ Meredith Lee Hill, *FDA chief: No one getting fired over baby formula crisis*, POLITICO (January 31, 2023).

⁴ See Joel Zinberg, *How the FDA bungled the nation's baby-formula supply*, N.Y. POST (June 2, 2022, 10:11 PM).

⁵ Statement from Robert M. Califf, Comm'r of Food and Drugs, F.D.A., FDA Proposes Redesign of Human Foods Program to Enhance Coordinated Prevention and Response Activities (Jan. 31, 2023).

Dr. Robert M. Califf

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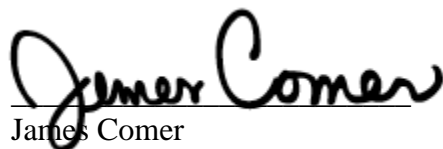
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1. All communications between or among the FDA, HHS, and White House staff referring or relating to the formula shortage;
2. All documents and communications relating to the development of the FDA's reorganization plan related to food safety and nutrition;
3. All documents and communications related to the search for and selection of a Deputy Commissioner for Human Foods;
4. All documents and communications related to the decision not to reassign or terminate the employment of any individual related to the infant formula shortage;
5. Documents sufficient to outline the processes and procedures for the transitions of FDA units affected by the reorganization; and
6. All documents and communications regarding a timeline for implementation of the reorganization.

To arrange for the delivery of responsive documents or ask any related follow-up questions, please contact the Committee on Oversight and Accountability Majority staff at 202-225-5074. Attached are instructions for producing the documents and information to the Committee.

The Committee on Oversight and Accountability is the principal oversight committee of the U.S. House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. Thank you in advance for cooperating with this inquiry.

Sincerely,



James Comer
Chairman
Committee on Oversight and Accountability



Lisa McClain
Chair
Subcommittee on Health Care and
Financial Services

cc: The Honorable Jamie Raskin, Ranking Member
Committee on Oversight and Accountability

The Honorable Katie Porter, Ranking Member
Subcommittee on Health Care and Financial Services