

Congress of the United States

Washington, DC 20515

July 28, 2023

Robert M. Califf, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

On June 27, 2023, the Food and Drug Administration (FDA) provided an update on its plans to reorganize the Human Foods Program and the Office of Regulatory Affairs (ORA). According to the announcement, the new Deputy Commissioner for Human Foods will have authority over “all budget and resource allocations for the [Human Foods Program], including ORA resources.” In addition, ORA’s compliance functions and laboratories will be merged into the Human Foods Program. We welcome this announcement and FDA’s attentiveness to the reorganization. It appears to be headed in the right direction.

In 2011, the *FDA Food Safety Modernization Act* (FSMA) was signed into law, to transform FDA into an organization that would prevent foodborne illnesses, rather than one that simply reacted to them after the fact. However, it is clear from the infant formula crisis and countless other incidents that FDA has not fully made that shift. More than a decade after FSMA was signed into law, our country still contends with far too many foodborne illness outbreaks every year, and tens of millions of Americans are sickened, more than 120,000 Americans are hospitalized, and 3,000 Americans die due to a foodborne illness.

Last winter, the Reagan-Udall Foundation conducted a review and found that the culture, leadership, and structure of FDA’s food offices prevented the agency from fulfilling its public health mission. As such, it recommended significant changes at FDA to address these issues, including through the appointment of a Deputy Commissioner for Human Foods and the integration of ORA into the Human Foods Program.

We are cautiously optimistic that FDA’s reorganization effort could improve the Human Foods Program, but we continue to urge FDA to heed the Reagan-Udall Foundation’s recommendations in full. Americans and their families deserve a Human Foods Program that is responsive to their needs and protects them from foodborne illnesses.

We appreciate FDA’s consideration of this letter and request answers to the following questions by **August 18, 2023**.

1. Please provide a breakdown of the roles and authorities of the new Deputy Commissioner for Human Foods and the Associate Commissioner for Regulatory Affairs.
 - a. Who will have decision-making authorities over imports, inspections, investigations, and recalls?
 - b. Please provide a “shared services budget,” as the Reagan-Udall Foundation called for in its report.
2. What mechanisms will be established to ensure the new Deputy Commissioner for Human Foods has “oversight of all budget and resource allocations” for the Human Foods Program?
3. What mechanisms will be established to ensure that the Associate Commissioner for Regulatory Affairs is accountable to the new Deputy Commissioner for Human Foods?
4. What are the specific compliance functions of ORA that will be moved under the Human Foods Program?
5. How will FDA’s reorganization of the Human Foods Program and ORA improve implementation of FSMA?
 - a. How will FDA’s reorganization shift the Human Foods Program from a reactive organization to a preventive organization? What are the specific mechanisms that will allow the Human Foods Program to prevent foodborne illness outbreaks?
 - b. How will FDA’s reorganization create more efficiencies and reduce the time between inspections and investigations?
 - c. FSMA directed FDA to “increase the frequency of inspection of all [food] facilities,” but inspections decreased instead. How will FDA’s reorganization of the Human Foods Program and ORA ensure that it meets this obligation?
6. How will FDA’s reorganization lead to more efficient communication and collaboration across the Human Foods Program, ORA, and the Office of the Commissioner?
7. How will FDA’s reorganization lead to more efficient communication and engagement with outside stakeholders?

Thank you for your consideration of this request. We look forward to your prompt response.

Sincerely,



Richard J. Durbin
United States Senator



Rosa L. DeLauro
Member of Congress