Congress of the United States

Washington, DC 20515

February 23, 2023

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

Dear Commissioner Califf:

We are writing to follow up on our January 30, 2023, letter in which we called for specific reforms to be implemented at the Food and Drug Administration (FDA) to better ensure the safety of our nation's food supply. We were pleased to see your announcement last month that you would implement some of our recommendations, including the appointment of a Deputy Commissioner for Human Foods. This is an important step, but we believe more can, and should be done. Notably, we continue to encourage you to integrate the Office of Regulatory Affairs' (ORA) food-related inspection responsibilities within the FDA's Human Foods Program, as recommended by the Reagan-Udall Foundation's report released in December 2022.

There are more than 81,000 domestic food facilities and 116,000 foreign food facilities registered with the FDA, which process most of the foods that Americans eat. It is critical that ORA inspect these facilities. But, for far too long, ORA has been asleep at the wheel.

The *FDA Food Safety Modernization Act* (FSMA) required FDA to "increase the frequency of inspection[s]" at all food facilities. The congressional intent behind this legislation was clear, but ORA did not follow through. In 2011, when FSMA was signed into law, ORA inspected 10,635 domestic food facilities. A decade later, in 2021, only 4,535 domestic food facilities were inspected—nearly a 60 percent decrease, despite the fact that ORA received additional authorities and tools through FSMA.

Further, in a 2017 report, the Department of Health and Human Services Office of Inspector General (OIG) found that, in the rare instance that an inspection was conducted, ORA did not "always take action when it uncovered significant inspection violations." Even when ORA acted, the OIG found that it relied on "facilities to voluntarily correct the violations," and did not "conduct timely follow-up inspections to ensure that facilities corrected significant inspection violations." This is unacceptable.

Your decision to allow ORA to maintain its food-related inspection responsibilities—despite its apparent inability to effectively carry out its regulatory duties—could result in the same dismal oversight and enforcement that Americans have been forced to live with over and over again.

Please reconsider this decision. ORA's work must be integrated within the Human Foods Program to "ensure that [the FDA's] field work aligns with the foods program policies" and to "facilitate the transformation of the inspectional service to the prevention model envisioned in [the] FSMA," according to the Reagan-Udall Foundation. If we want to make real, tangible improvements to our nation's food safety system, we must—at a minimum—find a way to

increase and improve FDA's facility inspection capabilities. Given that ORA has demonstrated time and again it is not up to the task, change is needed.

We commend you for the initial steps you have taken to improve FDA's food oversight program. But additional, bold action is necessary, in line with the recommendations from the Reagan-Udall report. We look forward to hearing back from you on this important matter.

Sincerely,

Richard J. Durbin
United States Senator

Rosa L. DeLauro
Member of Congress