February 6, 2023

Dr. Robert Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903-0002

Dear Dr. Califf,

As a broad coalition of FDA stakeholders, including industry and consumer groups and state food regulators, we appreciate the attention you have given to the problems in FDA's Foods Program, which were highlighted in the Reagan-Udall Foundation (RUF) report in December. We also are appreciative of your acknowledgment in your January 31 announcement that the Foods Program requires a leadership and management structure that enables it to fulfill its mission and is distinctive from the medical product programs.

The announcement contained some important positive elements – including creation of a deputy commissioner position with line management authority over the current CFSAN and the functions of ORA's state partnership office. It also indicated that certain other unspecified ORA functions "will be unified into a newly envisioned organization called the Human Foods Program." According to the announcement however, ORA's core food inspection, laboratory, compliance, and import oversight functions would remain in a separate ORA organization led by an Associate Commissioner for Regulatory Affairs (ACRA) reporting presumably to you.

Based on our understanding of this plan, it is difficult to reconcile this proposal with the analysis and findings in the RUF report. All five of the report's structural options included unifying ORA's operational functions with other elements of the Foods Program in a direct line reporting relationship to the top program leader. We are concerned that the plan does not include that, and thus does not create a unified foods program under a single leader.

Our concern about this is based on our extensive experience working with, and in some cases within, the FDA Foods Program, and encountering how its organizational fragmentation hinders coordination, collaboration, and the timeliness and consistency of decision-making. Currently, FDA's food-related operations are run by three large organizations – CFSAN, CVM and ORA – all reporting separately to the commissioner. It appears that this organizational fragmentation would continue within the newly proposed structure.

While the statement suggests the Deputy Commissioner would have "decision-making authority over policy, strategy, and regulatory program activities within the Human Foods Program, as well as resource allocation and risk-prioritization," we have concerns about whether and how this would work in the absence of line management authority. The RUF report closely links FDA's culture problems to its "disparate structure" and asserts that the Foods Program needs "a definitive and facilitative structure" and "a clear overarching leader." It also says that FDA's

culture issues were "foremost among the Panel's considerations when making recommendations for potential structural change."

On that basis, all of the RUF report's structural recommendations included having ORA's food functions reporting directly to the "single overarching leader." We recognize the challenges associated with shifting a deeply engrained culture, and proposing a structure that could be perceived as diminishing the autonomy of parts of the Agency. However, this is precisely what the RUF report suggests is needed to improve the function of the Agency.

Given our concerns, we request an opportunity to discuss the plan with you in person before it is finalized. The following questions reflect both our concerns and our uncertainties about how the envisioned plan would improve FDA's performance:

- Assuming the ACRA position continues to exist, what is the scope of its responsibilities? To whom would the ACRA report? Through what mechanism would the ACRA be accountable to the deputy commissioner?

- What is your vision for "transforming ORA's operating structure into an enterprise-wide organization that supports the Foods Program and all other FDA regulatory programs"?

- Would the deputy commissioner have direct management control over all food program activities, including ORA? How would this work in practice?

- Would the deputy commissioner have management authority to determine allocation of resources across ORA's food-related functions? For example, would the deputy commissioner be responsible for the formulation and execution of the entire foods program budget, including the portion of the Human Foods Program budget that ORA currently receives?

- Would the deputy commissioner have direct management authority over ORA's food operations, including inspection, compliance, lab operations, import oversight, training and IT?

- Would the deputy commissioner have management authority to conduct reviews of each of ORA's food-related functions and direct strategic and operational change?

- Would the deputy commissioner have authority to:
    - Establish position descriptions for ORA management and program staff?
    - Make selection decisions for ORA senior management positions?
    - Establish performance plans for ORA management positions?
    - Conduct performance evaluations of the ACRA and senior ORA managers and sign off on bonus recommendations?

- Would the deputy commissioner have complete access to all ORA food-related data and data systems and authority to redesign ORA data collection and analysis systems to meet the needs of the Human Foods Program?

- Would the deputy commissioner have management authority to direct how CVM conducts its operations related to food safety programs operating in the center?

- Would the deputy commissioner have authority to require scientifically appropriate harmonization among data and methods used to evaluate the safety for humans of food and feed additives and residues of animal drugs in human food?

- In what manner is the authority of the deputy commissioner codified in FDA's management system?

Thank you for your openness to a discussion with us on how best to prepare FDA's Food Program for future success. We hope that the plan remains open to the possibility for change that addresses our concerns and look forward to providing support for this challenging process.

Sincerely,

American Frozen Food Institute
Association of Food and Drug Officials
Consumer Brands Association
Consumer Reports
Environmental Working Group
International Fresh Produce Association
STOP Foodborne Illness
Western Growers