United States Senate
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS
WASHINGTON, DC 20510–6300

February 28, 2023

VIA ELECTRONIC TRANSMISSION

The Honorable Robert Califf, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration

Dear Commissioner Califf:

On January 31, 2023, the Food and Drug Administration (FDA) announced a new vision for the agency's Human Foods Program, as well as changes to the Office of Regulatory Affairs (ORA).[1] This planned reorganization comes after a 2022 *Politico* investigation that documented FDA's repeated failures to address food safety issues,[2] a U.S. Senate Health, Education, Labor, and Pensions (HELP) Committee hearing on the infant formula safety crisis,[3] and a report from experts convened by the Reagan-Udall Foundation[4] that catalogued the dysfunction and mismanagement in the foods program at FDA and called for significant changes to FDA's foods activities.

According to FDA's announcement, the agency plans to move the Center for Food Safety and Applied Nutrition, the Office of Food Policy and Response, as well as certain functions of ORA, into a newly formed organization called the Human Foods Program. Other key elements of this newly formed organization include the appointment of a Deputy Commissioner for Human Foods, the creation of a Center for Excellence in Nutrition, and the establishment of an Office of Integrated Foods Safety Systems Partnerships that will integrate FDA's food safety response activities with state and local regulators.

While we are encouraged by FDA's attention to reorganizing its operations, we are skeptical that the reorganization that FDA has proposed will actually solve the entrenched, systemic problems at the agency. This is why FDA's Human Foods Program will be a focus of the HELP Committee.

[1] Food and Drug Administration, "FDA Proposes Redesign of Human Foods Program to Enhance Coordinated Prevention and Response Activities," (Jan. 31, 2023) https://www.fda.gov/news-events/press-announcements/fda-proposes-redesign-human-foods-program-enhance-coordinated-prevention-and-response-activities.
[2] Politico, "The FDA's Food Failure," Botemiller Evich (April 8, 2022) https://www.politico.com/interactives/2022/fda-fails-regulate-food-health-safety-hazards/.
[3] U.S. Senate Health, Education, Labor, and Pensions Committee, "Infant Formula Crisis: Addressing the Shortage and Getting Formula on Shelves," (May 26, 2022) https://www.help.senate.gov/hearings/infant-formula-crisis-addressing-the-shortage-and-getting-formula-on-shelves.
[4] "Operational Evaluation of the FDA Human Foods Program: A Report of the Human Foods Independent Expert Panel," Henney, et. al (Dec. 6, 2022) https://reaganudall.org/operational-evaluation-fdas-human-foods-programs.

It is critical that FDA carry out its public health mission to protect American families from food-related emergencies and ensure that Americans have access to safe, healthy foods.

To that end, and consistent with your announced plans to provide additional public updates by the end of February, we ask that you answer the following questions on a question-by-question basis by **March 10, 2023**. We also request that all documents be produced electronically in PDF format.

1. What are the specific objectives that the proposed reorganization aims to achieve? Please explain in detail.

2. What specific metrics and measures will FDA use, on both an ongoing and periodic basis, to assess whether the reorganization is achieving its objectives and otherwise improving FDA's human foods operations?

3. Please produce a complete graphical organization chart of the proposed new Human Foods Program. Please also include:

    a. The number of employees and full-time equivalents (FTEs) proposed to support each part of the Program.

    b. How many will be existing FDA staff and how many will be new FDA hires?

    c. For existing FDA staff, from which parts of the agency will those employees be pulled?

    d. For new hires, what number will be hired using FDA's expanded hiring authority for the foods program provided in the 2023 Consolidated Appropriations Act?

    e. What funding will FDA use to make any new hires?

4. Both Michael Taylor and Dr. Stephen Ostroff previously oversaw FDA's food-related activities in a deputy commissioner role that was discontinued in 2019.

    a. What lessons has FDA learned from that experience that will be incorporated into the duties and activities of the new Deputy Commissioner for Human Foods?

    b. How will this position differ from Mr. Taylor's and Dr. Ostroff's responsibilities?

5. What specific activities will the Center for Excellence in Nutrition be responsible for conducting? Will it be akin to a traditional "center" at FDA, or more like a "Center of Excellence" (like those for oncology and digital health)? Why is this unit a "center," as opposed to an "office" or another organizational unit?

6. Following the infant formula crisis, Congress created the Office of Critical Foods in the 2023 Consolidated Appropriations Act to ensure accountability and oversight over critical foods (infant formula and medical foods), particularly with respect to safety.

a. Why is this Office being placed in the Center for Excellence in Nutrition instead of standing as a separate office within the Center for Food Safety and Applied Nutrition?

b. How will the placement of the Office of Critical Foods in the Center for Excellence in Nutrition improve safety oversight of infant formula and other critical foods?

c. What relationship do infant formula and medical foods have to a center that will be focused on "reduc[ing] diet-related chronic diseases and improv[ing] health equity"?

d. What is the relationship between the planned priorities of this Office and the other planned priorities of the Center for Excellence in Nutrition?

e. What activities will this Office be responsible for? Will these activities include oversight of facilities in which critical foods are made (including inspections)? If not, why not?

7. Please provide a detailed breakdown of the specific functions and duties that will be moving from ORA to the new Human Foods Program, and which functions and duties will stay with ORA.

    a. Will inspections of food facilities and farms be conducted by personnel in ORA, or in the Human Foods Program? If the former, why are food inspections staying within a centralized ORA, rather than being put under the umbrella of the foods program?

    b. What type of relationship will exist between the proposed newly reorganized ORA and the Human Foods Program? What kind of visibility will personnel in the Human Foods Program have into inspections and other activities (such as laboratory analyses) that may be conducted by personnel in ORA?

    c. What specific steps will you take to ensure that the problems observed during the infant formula crisis do not re-occur, and to ensure that the right decision makers in the agency will receive the timely information they need to address potential problems?

    d. Please provide a breakdown of the number of employees and FTEs who will be moving from ORA to the Human Foods Program, and the number of employees and FTEs staying in ORA who will work on food-related matters.

8. Please provide a detailed description of the specific functions and duties that will be performed by the proposed new Office of Integrated Food Safety System Partnerships.

    a. What interaction will this proposed office have with infant formula safety?

b. How will the proposed new office structure improve implementation of the Food Safety Modernization Act, such as through the conduct of inspections and sharing of information across what should be a national integrated food safety system?

c. Please provide a breakdown of the number of employees and FTEs who will be in this new Office.

Thank you for your attention to this letter.

Sincerely,

Bill Cassidy, M.D.
United States Senator

Roger Marshall, M.D.
United States Senator

Susan M. Collins
United States Senator

Mike Braun
United States Senator

Ted Budd
United States Senator