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

September 11, 2023

VIA ELECTRONIC TRANSMISSION

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

Dear Commissioner Califf:

Thank you for your March 10, 2023 response to our joint letter outlining additional details on how the Food and Drug Administration (FDA) intends to reorganize the Human Foods Program (HFP).[1] Ensuring that the reorganized HFP has a clear vision to protect public health is a priority for all stakeholders. However, you have yet to provide sufficient detail on how the HFP will accomplish this mission, instead pointing to the forthcoming reorganization plan that FDA plans to publish later this Fall.[2] FDA should not use the forthcoming plan to dodge congressional oversight over FDA's progress in improving food safety, and we will continue to press for answers to questions about how FDA will better protect American families from food safety events.

In light of the recent infant formula crisis, Congress needs more information to be able to assess FDA's planned reorganization. Nearly all of FDA's answers to our February letter provided little detail, punting to forthcoming announcements. Accordingly, when you release the reorganization plan this fall, we ask that you provide updated answers to the questions from our February letter on a question-by-question basis and that the reorganization announcement provide clear and comprehensive answers addressing these questions.[3] We would also request a staff briefing with the new deputy commissioner to better understand the changes made in the reorganization and the deputy commissioner's vision for implementing such changes. We expect that this plan will address the following points to ensure that American families have access to safe, nutritious food:

[1] *Ranking Member Cassidy, Colleagues Seek Clarity on FDA's Foods Reorganization*, Senate Committee on Health, Education, Labor & Pensions (February 28, 2023), https://www.help.senate.gov/ranking/newsroom/press/ranking-member-cassidy-colleagues-seek-clarity-on-fdas-foods-reorganization.
[2] *FDA Provides Update on Proposed Human Foods Program and Office of Regulatory Affairs Restructuring*, Food and Drug Administration (February 28, 2023), https://www.fda.gov/news-events/press-announcements/fda-provides-update-proposed-human-foods-program-and-office-regulatory-affairs-restructuring.
[3] That letter, dated February 28, 2023, is attached as Exhibit 1.

An Empowered Deputy Commissioner for Foods is Essential to Improve Food Oversight

One of the greatest challenges FDA's human foods program faces is the lack of a single voice to oversee the many functions FDA plays in ensuring food safety. Creating a new deputy commissioner for foods is a positive step, but the lack of clarity thus far leaves many unanswered questions about how this role will be able to successfully manage the HFP.

FDA had a similar deputy commissioner position from 2010-2019, but this role lacked the power needed to effectively manage food oversight.[4] While FDA has stated that this new role will oversee some of the responsibilities previously within the Office of Regulatory Affairs (ORA), the reorganization will still maintain ORA as a separate office.[5] Numerous stakeholders have raised concerns that failing to fully integrate ORA's food oversight within the HFP will deprive the new deputy commissioner of the ability to serve as an effective leader.[6] An empowered deputy commissioner is essential to properly manage the HFP. Consequently, FDA must provide greater detail about the authorities and responsibilities of the deputy commissioner and how regulatory duties will be divided between the HFP and ORA. This should include a specific accounting of the steps taken to ensure seamless coordination between HFP and ORA on food-related oversight activities. We look forward to hearing from the recently announced deputy commissioner on how he intends to fulfill this new role and effectively implement the planned reorganization.[7]

Clear Performance Metrics Are Needed to Measure the Success of FDA's Reorganization

Congress, FDA, and other stakeholders cannot evaluate whether the HFP reorganization is improving food safety without a framework to define goals and assess progress. Unfortunately, FDA has yet to provide such a framework or any details on how it will assess the HFP. FDA commonly releases strategic plans for other programs that measure progress across different metrics and issues quantitative status updates via FDA-TRACK. FDA must establish a similar framework to measure the reorganization and evaluate what more may need to be done to effectively regulate foods.

When the panel convened by the Reagan-Udall Foundation released its report evaluating FDA's foods program, it emphasized that cultural change is needed to improve food safety oversight.[8]

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[4] Megan Poinski, *FDA food safety chief Frank Yiannas resigns*, FoodDive (January 26, 2023), https://www.fooddive.com/news/fda-frank-yiannas-resigns/641300/.

[5] *FDA Provides Update on Proposal for Unified Human Foods Program, including New Model for the Office of Regulatory Affairs*, Food and Drug Administration (June 27, 2023), https://www.fda.gov/news-events/press-announcements/fda-provides-update-proposal-unified-human-foods-program-including-new-model-office-regulatory.

[6] *See, e.g.*, Deidre McPhillips, *FDA update on redesigned foods program sets final proposal for fall, draws disappointment from industry stakeholders*, CNN (February 28, 2023), https://www.cnn.com/2023/02/28/health/fda-food-program-update/index.html.

[7] *FDA Names First Deputy Commissioner for Proposed United Foods Program*, Food and Drug Administration (August 23, 2023), https://www.fda.gov/news-events/press-announcements/fda-names-first-deputy-commissioner-proposed-unified-human-foods-program.

[8] *Operational Evaluation of the FDA Human Food Program*, Reagan-Udall Foundation for the Food and Drug Administration (December 6, 2022), https://reaganudall.org/sites/default/files/2022-

Specifically, the report highlighted FDA's inability to make policy decisions, inhibiting successful regulatory actions.[9] While we appreciate FDA's recognition that a reorganization of its human foods program is necessary, we are concerned that FDA has not provided specific details about how it will foster an improved culture within the HFP.

FDA is responsible for protecting the public health and keeping the American food supply safe. As such, we look forward to FDA providing a clear vision for the HFP and outlining the program's strategic goals. Beyond the need for radical cultural change within this program, FDA must provide concrete, granular details in the upcoming reorganization plan specifying which metrics the agency will use to measure the HFP's performance over time. Each discrete part of the reorganized HFP should have its own metrics, tailored to the mission and functions of that organizational unit. These should include metrics both on activities and outcomes, such as:

- Activities
    - Number of State and FDA inspectors trained or re-trained on food safety and the consideration of company and facility food safety culture in prevention-oriented inspections;
    - Number of preventive control inspections and allocation of inspection time to prevention-oriented activities, including review of company food safety principles, food safety plans and programs, review of environmental monitoring records and actions taken in response to adulteration of product and/or contamination of environment, and assessments of what companies did to address process or product failures in the system;
    - Number of inspections, including number per type of product facility, and allocation of inspection time to educational activities, such as providing guidance documents and other activities to foster regulatory compliance and prevent food safety risks;
    - Number of prevention action plans developed and implemented to address the highest-priority risks, such as risks related to produce and non-produce foods, as well as chemical contaminants;
    - Number of follow-up inspections conducted within FDA's goal timeframe;
    - Number of guidance documents published and how those guidance documents relate to the overall strategic goals and priorities of the HFP;
    - Number of submissions reviewed (e.g., infant formula notifications, food additive petitions, food contact substance notifications, consultations on food from new plant varieties, etc.), and associated timelines.

- Outcomes
    - Number of food safety incidents (e.g., foodborne illness outbreaks);
    - Number of product recalls;
    - Number of product recall notices released within one day of initiation;

12/Human%20Foods%20Program%20Independent%20Expert%20Panel%20Final%20Report%20120622.pdf#page12.

[9] *Id*. at 11-12.

- Number of remedial actions, by type, to bring facilities into compliance successfully completed, and the timelines for implementing such actions.

The Office of Critical Foods Must Address Food Safety Issues

Congress established the Office of Critical Foods (OCF) in 2022 in response to the infant formula crisis to ensure accountability and oversight over the safety of infant formula and medical foods. FDA, however, intends to place OCF within its new Center of Excellence in Nutrition. Your response expanded on this decision, emphasizing that FDA considers critical foods to be a subset of nutrition work, pointing to these foods as "a sole source of nutrition for vulnerable populations."[10]

We remain concerned that placing the OCF within the new nutrition-focused Center of Excellence will detract from its intended mission to oversee the safety and supply of critical foods. It is essential that FDA provide greater detail in the upcoming reorganization plan on how it intends to structure the OCF within the Center of Excellence and prioritize its mandate to oversee the safety and availability of critical foods.

FDA Must Work with Other Agencies to Improve Food Oversight

As FDA implements the HFP reorganization, it should also consider how to improve its partnerships with other federal agencies involved with food safety. Both the Centers for Disease Control and Prevention (CDC) and the Department of Agriculture (USDA) play a role in monitoring foodborne illnesses and supporting the development of innovative foods.

It is unclear how well the food safety agencies are working together to carry out their respective responsibilities. For example, CDC has failed to regularly update its data on foodborne illness incidence, last publishing a report on foodborne disease surveillance reflecting events in 2017.[11] Additionally, CDC continues to use outdated information to estimate foodborne illness incidence, relying on data from 2006.[12] FDA, however, collects extensive and up-to-date information related to recall events and preventive controls to ensure food safety.[13] FDA should be working with CDC and USDA to maximize interagency activities to protect public health, including sharing updated data between agencies to inform cross-agency priorities. We ask that FDA provide additional detail in the upcoming reorganization plan on how it intends to improve its engagement with other federal stakeholders and leverage updated information to inform HFP's activities.

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[10] *See Letter to Senator Bill Cassidy et al*., Food and Drug Administration (March 10, 2023), at 5.
[11] *Annual Summaries of Foodborne Outbreaks*, Centers for Disease Control and Prevention (September 12, 2019), https://www.cdc.gov/fdoss/annual-reports/index.html.
[12] *Estimated Annual Number of Illnesses Caused by 31 Pathogens*, Centers for Disease Control and Prevention (November 8, 2018), https://www.cdc.gov/foodborneburden/index.html.
[13] *FDA-TRACK: Preventive Controls and Current Good Manufacturing Practice Measures*, Food and Drug Administration (May 19, 2023), https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-preventive-controls-and-current-good-manufacturing-practice-measures#4.

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We look forward to reviewing the final reorganization plan this fall and working with you and other stakeholders to ensure FDA's foods program is best equipped to protect food safety.

Sincerely,

Bill Cassidy, M.D.
United States Senator

Roger Marshall, M.D.
United States Senator

Mike Braun
United States Senator

Ted Budd
United States Senator

Copy:

The Honorable Tom Vilsack
Secretary, U.S. Department of Agriculture

Dr. Mandy K. Cohen
Director, Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

Exhibit 1

February 28, 2023 Letter to FDA Commissioner Robert Califf, M.D.

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