U.S. FOOD & DRUG ADMINISTRATION

March 9, 2023

Brian Ronholm
Director, Food Policy
Consumer Reports
101 Truman Avenue
Yonkers, NY 10703

Dear Mr. Ronholm:

Thank you for your letter sent on February 6, 2023, along with seven other co-signers. Thank you to you and the other coalition members for meeting with me on February 14 and February 27, 2023, as well as participating in other meetings throughout this year regarding FDA's Human Foods Program (HFP). Your letter raises a number of questions, to which I will respond in some detail below.

Your coalition's public recognition that our January 2023 announcement contained positive elements including – the creation of an empowered Deputy Commissioner position and an Office of Integrated Food Safety System Partnerships within the newly envisioned Human Foods Program (HFP) – is appreciated. FDA believes this new Office will elevate our food safety system partnerships with co-regulators and bolster our nation's food safety system. Although experts agree that the food supply in the United States is as safe as it has ever been and at least on par with other high-income countries, FDA is committed to continuing to make progress through strategies like targeted product-pathogen prevention efforts and tech-enabled, data driven risk prioritization as well as stronger reliance on our regulatory partners.

Let me clearly address the principal concern that your coalition has raised about the future of the HFP, namely that the new position of Deputy Commissioner will not have the authority and capability to carry out the program improvements that former FDA Commissioner Henney's group recommended, and that I agree with. It is imperative that you understand that I intend for the Deputy Commissioner for the HFP to have full management and operational authority over all aspects of the food program and its resources. Indeed, this leader will:

- Be empowered to make any and all executive decisions with respect to the policies and operations of the human foods program, whether in headquarters or the field;
- Be the lead official in establishing priorities for food program activities, including risk prioritization for inspections and compliance activities and a clear movement toward the preventive controls regime directed by the Food Safety Modernization Act;
- Prepare and defend food program budgets, including budgets for both headquarters and field functions; and
- Determine the allocation of food resources, including headquarters, field

operations, and other food program resources.

I do not intend for the Deputy Commissioner for Human Foods to be saddled with day-to-day operational oversight of the portions of the field workforce that carry out ORA's traditional field responsibilities, such as inspections, imports, field laboratory operations, and criminal investigations. The public health does not benefit from mandating the Deputy Commissioner manage an inspectorate's car fleet, maintenance of field offices and laboratories, booking travel for inspectors, developing modern information systems, ordering IT equipment for field staff, badging and credentialing inspectors, and the many other hundreds of activities that are most efficiently managed at the enterprise-wide level. FDA achieves great efficiency and operational expertise from having a single field organization.

However, because the Deputy Commissioner will be authorized to set priorities, manage resource allocations, and establish compliance policy, I am confident that this leader will have sufficient empowerment over field operations. Concept of operations documents and processes will be created that will clarify roles and responsibilities in such a way to dispel any doubts about my intentions to empower the Deputy Commissioner with the authority to oversee and manage the human foods program in its entirety.

It would be easy for FDA to move a few organizational boxes around – but I intend to fix the fundamental organizational issues in our foods and field programs. This includes modernizing inspectional and compliance processes, defining decision rights, mapping resource allocation to allow risk prioritization, improving operational relationships between field and program laboratories, enacting an enterprise-wide transformation of how the entire field workforce operates, realigning state and local partnership programs, and redesigning the Human Foods Program from stem to stern. These are not superficial fixes – these are fixes that will deliver a program that operates with maximal agility, effectiveness, and efficiency.

I must point out that the letters from your coalition have not acknowledged a critical foundational element of FDA's new vision – the elevation of program elements that address chronic health risks and the ability to better leverage the best available science and data to allow FDA to prioritize and manage risks. To catalyze a renewed approach to diet-related chronic disease, we will create of a Center for Excellence in Nutrition. Only approximately $29 million, three percent of FDA's food resources, are currently dedicated to nutrition. However, nutrition-related chronic diseases are major contributors to illnesses and deaths in this country. A 2022 analysis of life expectancy in the United States shows that an American now dies over five years earlier, on average, compared to peer high-income nations[1], and much of this decline and widening difference is due to common chronic diseases with a significant nutritional component. A 2021 Government Accountability Office report[2] cited the following:

- Forty two percent of American adults are obese and thus at higher risk for morbidity and mortality – this is over 100 million Americans;

[1] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2791004
[2] https://www.gao.gov/assets/gao-21-593.pdf

- Cardiovascular disease, cancer, and diabetes accounted for half of all annual deaths in the U.S. – approximately 1.5 million deaths;
- People living in southern states, men, rural and Black Americans had disproportionately higher mortality rates than those living in other geographic locations, women, and other races; and
- Government spending, including Medicare and Medicaid, to treat cardiovascular disease, cancer, and diabetes accounted for 54 percent of the $383.6 billion in health care spending to treat these conditions.

Your letters have not addressed chemical safety and new technological innovation. The food industry is transforming the marketplace with new ingredients constantly, and yet, compared to our remit, the chemical safety and food additive programs are small and have been consistently under-resourced. This comes at a time where consumers are increasingly seeking more oversight from FDA on the chemicals being added to foods. The new HFP will greatly increase its efforts to understand the potential risks of chemicals in the food supply and prioritize our risk management activities to match the level of risk. The new HFP will also increase its focus on innovation in the food supply – which holds the promise to deliver new choices to consumers and help our food supply become more resilient in the face of climate change, supply chain disruptions and global strife.

Your coalition asserts that a matrix model with clearly defined authorities and decision rights will not work for the Human Foods Program – or in government writ-large. Matrix models are the current best organizational practice as they leverage multi-disciplinary expertise and teams while still ensuring clarity in who is in charge. Simply put, creating rigid, command and control models leaves an organization brittle and unable to respond to dynamic problems. FDA has proven matrix models can work. For example, FDA has a matrixed relationship with CDC when it comes to investigating foodborne outbreaks. FDA has a matrixed relationship with the U.S. Department of Agriculture on the regulation of cell cultured foods. FDA and its federal partners have a matrix relationship for the federal government's approach to the regulation of biotechnology. FDA's drug regulatory program is fully matrixed, and the medical product centers have matrix models when it comes to the regulation of combination products. FDA's regulatory programs also have matrixed relationships to enterprise-wide functions like congressional affairs, global affairs, and human resources, and their ability to best support the HFP is strengthened in my vision as they are not having to navigate among interests from CFSAN, OFPR, and ORA, but rather working to support the direction of the empowered Deputy Commissioner for Human Foods.

Finally, I want to respond to your coalition's continued advocacy that FDA's Center for Veterinary Medicine be subsumed under a Deputy Commissioner focused on human food issues. This stance fails to recognize the unique breadth of CVM. The majority of CVM's work is on animal drugs. For example, in 2021, CVM approved a new lymphosarcoma treatment for dogs and in 2022, it approved a new antibody treatment for arthritis pain in cats – critical veterinary medical innovations that are more akin to work at FDA's medical product centers. Further, many of CVM's animal feed safety issues are unique to animals and do not relate to human food safety – for example, diets for cats with insufficient taurine prove a significant health risk to cats, since they cannot synthesize this essential amino acid. FDA has met with multiple other food,

animal, and veterinary stakeholders who have advocated for CVM to report directly into the Commissioner given previous experience that Deputy Commissioners focused on human food issues deprioritized animal health and veterinary medical issues. However, as I have stated to you, clear matrix decision and authority rights between the HFP and CVM will be defined where CVM's work implicates human food safety and nutrition. This will mean that CVM will be integrated and responsive to the HFP on these matters.

Looking ahead to the future, I share your coalition's goal to recruit a strong, talented leader for the future Human Foods Program at FDA – this position will have a generational opportunity to impact the future of the nation's food supply and health. However, I have received feedback from potential candidates for the Deputy Commissioner for Human Foods job that the tenor of some of the public criticism of FDA's foods program is dissuasive.

I am proud to lead the most dedicated, accomplished public health workforce in the world. This workforce continues to protect consumers everyday – work that includes outbreak investigations, inspections, pre-market reviews of new food additives, and hundreds of other activities. Your letter notes the criticality of cultural transformation at FDA, and successful cultural transformation efforts will be set back if the workforce is demoralized, or consumers lose confidence in what is demonstrably a food supply that is as safe as it's ever been. Criticism that is more corrosive than constructive works against our mutual goals.

I have received in multiple meetings and correspondence your views that direct the Agency to adopt a singular solution based on antiquated command and control organizational concept on to whom specific positions should report, or that otherwise a new agency should be created. I hope this letter makes clear that the Agency has carefully considered but disagrees with this concept and is working hard to design the vision we have announced, which I am confident will produce the outcomes you want.

Therefore, I ask you to consider ways to provide the Agency the most constructive feedback possible while taking our mutual goals into account. I welcome constructive criticism and I and other leaders of the HFP would like to continue to engage your coalition on specific, concrete ideas and solutions on how to make FDA's envisioned framework maximally successful. In addition to food safety inspections, I would also appreciate your coalition's specific feedback on the issues of nutrition, chemical safety, and innovation.

I am providing the enclosed responses to the eleven questions your letter poses to the extent possible, given that we are in the early design phase of a reorganization and transformation effort and some details are not yet available.

Sincerely,

Robert M. Califf, M.D.
Commissioner of Food and Drugs

Enclosure: Interim Responses to Questions

Enclosure – FDA Interim Responses to Questions

Enclosed are response to your questions. These responses are interim as for some questions, FDA is too early in the organization redesign process to have a definitive or complete response.

1. **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?**

Response: Yes, an executive position over the FDA field workforce will continue to exist and report to the Commissioner. There are important operational field-wide activities that still need to be led and managed.

The Human Foods Program will be empowered with clear decision rights over key activities like resource allocation, strategic direction, risk prioritization, and cultural transformation to build a high-functioning food safety team. The Deputy Commissioner for Human Foods will have the final say over these and other to be defined decision rights – which will be established in clear, publicly-available operating procedures and concept of operations.

FDA envisions the ACRA will have a critical role to manage day to day the global operations and logistics of an Agency-wide field force focused on its core activities – inspections, imports, sample analysis, and investigations. The field force will be increasingly professionalized, specialized, and integrated into the regulatory programs. The ACRA will also lead efforts to deliver the most effective and efficient enterprise-wide logistics and operational excellence of field activities, and the programs, including the Deputy Commissioner for Human Foods, will reap the benefits of these efficiencies.

2. **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"?**

Response: FDA intends to deliver a field workforce that is focused on its core activities of inspections, investigations, import operations, and sampling analysis – and that the field workforce will be directly integrated in working with and at the direction of the programs. To do this, FDA has started several work streams

including assessing how to streamline inspection and compliance processes and assessing moving some functions from ORA into other parts of the Agency. Please see FDA's February 28, 2023 announcement for more details.[3]

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

Response: Yes, FDA envisions the Deputy Commissioner will have clear management and decision rights over major activities – including resource allocation, strategic direction, risk prioritization, and cultural transformation to build a high-functioning team for food safety. FDA envisions that the Deputy Commissioner would set the priorities for field activities, direct how the resources will be used, what risks will be prioritized, and inspection strategy (such as development of new inspection methods or specialized training for inspectors, recruitment goals and attributes for inspection workforce, etc).

4. **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?**

   Response: Yes, the Deputy Commissioner for Human Foods will have the final decision rights on the allocation of all Human Foods program resources – including resources allocated for field activities.

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

   Response: Yes, the Deputy Commissioner for Human Foods will have authority to set strategic direction, resource allocation, and risk prioritization for these field operations. FDA notes that some of these functions are being assessed for potential realignment into the Human Foods program or as enterprise-wide services. For example, as announced last week, FDA is

[3] https://www.fda.gov/news-events/press-announcements/fda-provides-update-proposed-human-foods-program-and-office-regulatory-affairs-restructuring

assessing moving IT functions to the Office of Digital Transformation, to deliver enterprise-wide inspection and work planning platforms that all parts of the Agency can access in real-time. FDA is also assessing whether some training functions for field staff might be realigned into the Human Foods program. For example, FDA envisions the ACRA will set foundational inspection and investigations method training as well as credentialing for the inspectorate, while the programs will lead training and method development on specialized commodities or public health goals – such as infant formula and the prevention of *Cronobacter* contamination.

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

Response: Yes, the Deputy Commissioner for Human Foods will have authority to set strategic direction, resource allocation, and risk prioritization for these field operations, and to do this may need to evaluate field functions.

7. **Would the deputy commissioner have authority to:**
    a. **Establish position descriptions for ORA management and program staff?**

        Response: No, the day to day drafting of thousands of field staff position descriptions or jobs announcement is an important function that best resides elsewhere. Some of this work is managed at the enterprise-level in FDA's Office of Talent Solutions to ensure Agency-wide compliance with Federal human resource requirements, and other functions will reside in the field organization. However, the Deputy Commissioner will have authority to set strategic direction – for example – FDA envisions the Deputy Commissioner could direct the establishment of a specialized inspection cadre and provide high-level input on attributes and goals for staffing.

    b. **Make selection decisions for ORA senior management positions?**

        Response: The Deputy Commissioner will have input into recruitment of ORA senior managers involved in the HFP, although the exact level of this involvement will be defined later in the process.

c. Establish performance plans for ORA management positions?

Response: FDA has not yet determined the level or type of involvement the Deputy Commissioner would have in establishing performance plans for executives managing human food operations in the field program, but it is a fundamental attribute of a matrix organization that the HFP will have significant input into assessment of job performance for ORA executive positions relevant to the Human Foods Program's mission.

Conduct performance evaluations of the ACRA and senior ORA managers and sign off on bonus recommendations?
Response: FDA has not yet determined the level or type of involvement the Deputy Commissioner would have in conducting performance reviews for executives managing human food operations in the field program, but it is a fundamental attribute of a matrix organization that the HFP will have significant input into assessment of job performance for ORA executive positions relevant to the Human Foods Program's mission.

8. 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?

Response: Yes, FDA's goal is to adopt dynamic, enterprise-wide IT systems managed by FDA's Office of Digital Transformation, which resides in the Office of the Commissioner. The Deputy Commissioner will have full access to all parts of this system relevant to the Human Foods Program.

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

Response: The Deputy Commissioner will be empowered over key decisions that impact the Human Foods Program, but FDA is still early in this transformation and reorganization design process. This will be defined by clear concept of operations and operating procedures. FDA expects CVM will be significantly integrated into the Human Foods Program where its activities are relevant.

FDA notes that some decisions relevant to Human Foods may appropriately reside with the Director for Veterinary Medicine, particularly when it comes to the new animal drug review process, which are governed by specific statutory and regulatory requirements and procedures. FDA further notes that not all CVM food safety activities are relevant to the Human Foods Program. There are dozens of food safety or nutritional requirements specific to the safety of animals – such as ensuring diets for cats have adequate levels of taurine, since this species cannot synthesize this essential amino acid and must rely on its diet to obtain it.

10. **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?**

    Response: FDA has not yet determined the level or type of involvement the Deputy Commissioner would have in these processes but expects clear decision rights between the Deputy Commissioner for Human Foods and Director of the Center for Veterinary Medicine will be established for them. FDA has a goal, however, to harmonize and integrate activities like plant biotechnology that currently have processes that reside both at CFSAN and CVM, and where the Agency needs to take an agile, unified approach to embrace innovation and ensure safety in the food supply.

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

Response: FDA intends to codify this in written operating procedures and in appropriate staff manuals, where it will be publicly available, so all internal and external stakeholders know who has the ultimate authority or decision right.