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FDA STATEMENT

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FDA Proposes Redesign of Human Foods Program to Enhance Coordinated Prevention and Response Activities

The following is attributed to FDA Commissioner Robert M. Califf, M.D.

As the oldest comprehensive consumer protection agency in the country, for more than a century the U.S. Food and Drug Administration has been responsible for ensuring the safety of food products consumed by hundreds of millions of Americans each year while also advancing nutrition. It is our mission to ensure that our programs are organized in a manner that will protect and promote public health.

The agency has carefully reviewed the findings and recommendations from an external evaluation conducted by an expert panel of the Reagan-Udall Foundation that I requested and a separate internal review of the agency's infant formula supply chain response completed last year. The findings and recommendations from these reviews identified issues surrounding culture, structure, resources, and authorities. They also noted several areas of need, including modernizing data systems, providing more resources (staffing, training, and regulatory authorities), improving emergency response systems, and building a more robust regulatory program.

Today I am announcing a new, transformative vision for the FDA Human Foods Program. I am also announcing the transformative vision for the Office of Regulatory Affairs (ORA, the FDA's field-based operations) to support the FDA organization as a whole. The proposed structures for both groups will have clear priorities that are focused on protecting and promoting a safe, nutritious U.S. food supply that more quickly adapts to an ever-changing and evolving environment. I believe this proposed approach addresses the recommendations outlined in both reports, and takes into consideration feedback from stakeholders, as well as the voices of employees working in the Human Foods Program who had an opportunity to share input through numerous interactive and listening sessions over the past month. Creating a human foods program under a single leader who reports directly to the Commissioner unifies and elevates the program while removing redundancies, enabling the agency to oversee human food in a more effective and efficient way.

Under this plan, the functions of the Center for Food Safety and Applied Nutrition (CFSAN), Office of Food Policy and Response (OFPR), as well as certain functions of ORA will be unified into a newly envisioned organization called the Human Foods Program. The FDA will conduct a competitive national search for a Deputy Commissioner for Human Foods, who will oversee the Program. The person in this position will report directly to me and will be charged with leading a unified Human Foods Program that keeps the foods we regulate safe and nutritious, while ensuring the agency remains on the cutting edge of the latest advancements in science, technology, and nutrition. The Deputy Commissioner will have decision-making authority over policy, strategy, and regulatory program activities within the Human Foods Program, as well as

resource allocation and risk-prioritization. Other key elements of the proposed new Human Foods Program organization include:

- Creation of a Center for Excellence in Nutrition that prioritizes the agency's ongoing efforts to help American consumers make more informed food choices, including by working with industry to offer healthier, more nutritious food products. The FDA will establish an Office of Critical Foods, as directed by the 2023 Consolidated Appropriations Act, within this center.
- Establishment of an Office of Integrated Food Safety System Partnerships that will focus on elevating, coordinating and integrating our food safety and response activities with state and local regulatory partners to more effectively meet the vision of an Integrated Food Safety System as envisioned in the FDA Food Safety Modernization Act of 2011. This newly proposed structure will ensure greater collaboration and support of state-level inspectional activities. We know that we cannot be everywhere, at all times, and our relationships with our state and local regulatory partners will be more important than ever going forward.

To help support the agency's scientifically grounded decision-making activities, a Human Foods Advisory Committee will be established. Advisory Committees are commonly used to obtain independent expert advice on various issues. The Human Foods Advisory Committee will consist of external experts to advise on emerging issues in food safety, nutrition and innovative food technologies.

Finally, there will be an emphasis on strengthening our enterprise information technology and analytical capabilities to fulfill the promise described in the New Era of Food Safety and the improvement in workflow that will accompany these changes. This area of focus will support the work of the Human Foods Program by enabling more facile communication, more efficient operations and enhanced empirical risk algorithms to guide the priorities of the program and the work in the field.

As part of this proposed new vision, ORA's operating structure will be transformed into an enterprise-wide organization that supports the Human Foods Program and all other FDA regulatory programs (e.g., agency centers) by focusing on its critical activities. This realignment will allow ORA to be singularly focused on excellence in its core mission – inspections, laboratory testing, import, and investigative operations. This will optimize ORA's operations in line with the FDA's public health and prevention-oriented goals. Certain other functions of ORA will be aligned in other parts of the FDA to create an overall stronger agency.

While the FDA's Center for Veterinary Medicine (CVM) will continue to operate as a stand-alone center, the relevant food safety activities will be closely coordinated between the CVM Center Director and Deputy Commissioner for Human Foods. This proposed structure will allow CVM to support the Human Foods Program where its activities are relevant to human food safety.

The FDA has recently formed an Implementation and Change Management Group that will be charged with developing a detailed plan to ensure the successful execution of this vision.

Consumers can be confident in the safety of the food they eat each day in part thanks to the work of the FDA's dedicated workforce. Our ability to continue our work means consistently evolving and adapting with the constantly changing, complex industries we regulate and the emergence of new technologies. As a next step, the FDA will need to develop the vision announced today into a concrete reorganizational proposal in close coordination with internal

and external stakeholders while ensuring we meet our labor obligations. While details of this proposal continue to be developed, CFSAN, ORA, and OFPR will continue to operate under their current structures, with my direct oversight. I look forward to providing additional public updates by the end of February on our progress, organizational design and timeline.

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