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FDA Obtains Approval for Massive Reorganization – What It Means for the Food Industry

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On May 30, FDA announced that it has received approval for its planned reorganization to establish the Unified Human Foods Program. FDA has targeted Oct. 1, 2024 for the reorganization implementation, which will impact 8,000 FDA employees. The impact of the FDA's reorganization on FDA-regulated consumer products like foods, dietary supplements and cosmetics is likely to be significant in the coming months and years. Here is a refresher on the planned changes and what to expect next.

What is FDA planning?

Over the coming months, FDA expects to complete a transformative realignment of its disparate food centers and offices into a Unified Human Foods Program ("HFP"). FDA is betting that this reorganization will enable more effective, centralized management of the Agency's food oversight plus swifter response to emergencies.

FDA is dismantling two major scientific and regulatory centers and merging them into a single organization under a single leader – Deputy Commissioner Jim Jones – who reports directly to FDA Commissioner Robert M. Califf. This new organization will also absorb certain food-related activities of the Office of Regulatory Affairs, which itself will be transformed into a new field organization focused solely on inspections, investigations, and imports.

Why is FDA taking these steps?

FDA's current Center for Food Safety and Applied Nutrition has developed an unfortunate reputation among both industry and consumers as being slow, non-responsive, and somewhat ineffective. FDA developed the proposed organizational changes after a year of gathering feedback, criticism, and advice about its slow and fragmented response to the infant formula outbreak in February 2022. This emergency saw a large-scale, voluntary recall of contaminated infant formula and severe shortages.

FDA's internal review concluded that FDA was poorly equipped to respond to the emergency, that its activities lacked clarity regarding roles and responsibilities, and that its actions suffered from poor coordination among various centers and offices across the Agency.[1]

FDA also asked the nonprofit Reagan-Udall Foundation for an independent review and recommendations. The Foundation issued a report finding that a lack of communication and engagement across the Agency contributed to the poor response: "While it appears that staff at all levels sought to follow the rules and procedures within their division, there was little motivation, and apparently no requirement, to share information and interact across the Agency to facilitate critical thinking and proactive decision-making." [2]

[1] "FDA Evaluation of Infant Formula Response," Dr. Steven M. Solomon, September 2022, p. 6.
[2] "Operational Evaluation of the FDA Human Foods Program," Reagan-Udall Foundation for the FDA, December 2022, at p. 12.

The Foundation said FDA employees "often operate in silos within the organizations or subcultures where they feel most valued and comfortable."[3] While the Agency has a dedicated staff committed to protecting public health, the Foundation found that food activities were spread over offices that had competing priorities and operated on a consensus model that inhibited the ability to respond swiftly and effectively to a crisis.

The Foundation concluded that FDA's human foods program sorely needed a single, strong, empowered leader: "The lack of a clear, overarching leader of the Human Foods Program has contributed to a culture of indecisiveness and inaction and created disincentives for collaboration."[4] This observation formed the core of FDA's vision for reorganizing its human foods program.

What specific changes does FDA plan to make?

The realignment calls for two major steps:

1. Merging two centers of scientific / regulatory expertise – the Center for Food Safety and Applied Nutrition ("CFSAN") and the Office of Food Policy and Response ("OFPR") – into the HFP, along with and certain food compliance functions of the current Office of Regulatory Affairs ("ORA"); and

2. Creating a new Office of Investigations and Inspections ("OII") that will take the place of ORA and focus on inspections, laboratory testing, imports and investigations across all FDA-regulated products, including foods. FDA characterizes this new office as an "enterprise-wide organization" supporting HFP and all other FDA regulatory centers. The OII will include an "Office of Human Food Inspectorate" to manage food inspections.

Jim Jones, recently appointed Deputy Commissioner for Human Foods, will lead the HFP, and an Associate Commissioner for Inspections and Investigations will lead the OII. FDA's other product centers – veterinary medicine, drugs, biologics and medical devices – will remain independent and intact, with some strengthened with additional personnel. CFSAN activities concerning cosmetics, medical products and specialty labs will move into FDA's Office of the Chief Scientist.

What will the new HFP look like?

FDA has touted the advantages of this reorganization, saying that it will bring together the food activities of three disparate groups – CFSAN, OFPR and ORA – into a single organization focused on human food. The new organization will include three offices with responsibilities for managing public health risk:

- The **Nutrition Center of Excellence** will work to reduce diet-related chronic diseases and, housing the Office of Critical Foods, will work to ensure the safety and adequacy of infant formula and similar critical foods;

- The **Office of Microbiological Safety** will promote pathogen reduction strategies and focus on reducing pathogen-related food-borne illness; and

[3] *Id.*
[4] *Id.*, at p. 11.

- The **Office of Food Chemical Safety, Dietary Supplements and Innovation** will oversee the safety of food chemicals and dietary supplements and regulate ingredient innovation through the food additive review and GRAS notification processes.

FDA also announced that the HFP and the other product centers would be solely responsible for receiving, reviewing, and closing consumer and whistleblower complaints. In the past, this work had been split between the product centers and the ORA field offices.[5] FDA is hoping that this change will improve its ability to detect and solve problems faster.

The HFP reorganization establishes several "Cross-Cutting Functions" designed to help speed the response to outbreaks, work closely with state and local regulators and coordinate FDA's own compliance and enforcement activities, among other things. Under the authority of Food and Drug Omnibus Reform Act of 2022, FDA is also creating an Office of Critical Foods to focus on the oversight of infant formula and other essential food products.

What will these changes mean for the food industry?

The HFP will need time to find its footing and become fully functional. Specific impacts will take time to emerge. However, food manufacturers should bear in mind that once the HFP is in place, they will face a centralized FDA regulatory structure empowered to set public health priorities and coordinate enforcement across the food supply. The immediate effects are most likely to be seen in the conduct of inspections and the management of product emergencies.

Food inspections are likely to become more frequent and focused on risk priorities articulated by the HFP and executed by the Human Foods Inspectorate within the OII. Given what FDA has already said about Agency priorities, manufacturers can expect FDA inspectors to be keenly focused on the implementation of FSMA. Manufacturers must establish well-documented preventive controls programs and be prepared to share plans and records proactively with Agency officials. In addition, manufacturers should expect a faster and more unified response from the Agency. Indeed, the entire HFP was designed so as not to repeat the missteps of the infant formula crisis. This organized structure should foster speedier resolution of investigations, recalls and other emergency situations.

What could continue to impede FDA's progress to strengthen its foods program?

FDA's food funding has long lagged behind its funding for other regulated products (such as drugs and devices) and because the foods program is not planned to have meaningfully increased user fees, the gap will remain. FDA's reorganization plan is ambitious but is expected to be budget neutral. While FDA's requested future budget includes additional funding for the foods program, even if FDA obtains the full funding requested, it may still find that its resources pale in comparison to the tasks at hand. Still, industry would be wise to take note of the budgetary priorities that FDA has publicized for the HFP and for which it has requested additional funding, including an emphasis on improving nutrition to reduce chronic disease (*e.g.*, a final healthy nutrient content claim rule and continued efforts to reduce sodium, added sugar, and saturated fat), food chemical safety (including reassessments of high-priority chemicals), and enhancing food safety.

[5] News Release, "FDA Advances Reorganization Proposal for Unified Human Foods Program, Field Operations and Additional Modernization Efforts: Additional Changes Showcase Agency-wide Impact of Proposal," Dec. 13, 2023.