ENERGY & COMMERCE
CHAIR RODGERS

MEMORANDUM

To: Subcommittee on Health Members and Staff
From: Committee on Energy and Commerce Majority Staff
Re: Health Subcommittee Hearing on September 10, 2024

The Subcommittee on Health will hold a hearing on Tuesday, September 10, 2024, at 10:00 AM (ET) in 2123 Rayburn House Office Building. The title of the hearing is "Evaluating FDA's Human Foods and Tobacco Programs."

I. Witnesses

- **Mr. James "Jim" Jones,** Deputy Commissioner for Human Foods, U.S. Food and Drug Administration
- **Dr. Brian King, Ph.D.,** Director, Center for Tobacco Products, U.S. Food and Drug Administration

II. Background

FDA Mission and Structure

First established in 1906, the U.S. Food and Drug Administration (FDA) was created to promote and protect the public health through the regulation of human and veterinary drugs, biological products, tobacco, cosmetics, medical devices, food, and electronic products that emit radiation. FDA-regulated products account for about 21 cents of every dollar spent by U.S. consumers.[1] In total, the FDA oversees more than $3.6 trillion worth of food, tobacco, and medical products produced in the U.S. and abroad.[2]

The FDA currently employs more than 18,000 people in all 50 states and in international outposts.[3] It is made up of nine centers and 13 offices.[4] This hearing will focus on (1) the unified Human Foods Program (HFP) and (2) the Center for Tobacco Products (CTP).

The Human Foods Program

The FDA regulates nearly 80 percent of the U.S. food supply through its Foods Program. Nearly every food product is subject to FDA regulation, except for meat, poultry, and some egg

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[1] U.S. Food and Drug Administration, "FDA at a Glance," 2024, https://www fda.gov/media/175664/download.
[2] *Id.*
[3] U.S. Food and Drug Administration, "About FDA," https://www.fda.gov/about-fda#:~:text=Each%20day%20in%20America%2C%20you,%2C%20biologics%2C%20and%20medical%20devices.
[4] U.S. Food & Drug Administration, "FDA Organization Charts," 2024, https://www fda.gov/about-fda/fda-organization/fda-organization-charts.

products.[5] Within the Human Foods Program, the Center for Food Safety and Applied Nutrition (CFSAN) is responsible for: (1) conducting and supporting food safety research; (2) developing and overseeing enforcement of food safety and quality regulations; (3) coordinating and evaluating the FDA's food surveillance and compliance programs; (4) coordinating and evaluating cooperating states' food safety activities; and (5) developing and disseminating food safety and regulatory information to consumers and industry.[6] The FDA partners with state and local regulators to administer and enforce laws related to food safety, with state agencies conducting most inspection activities.

Congress passed the Food Safety Modernization Act in 2011 granting the FDA new authorities to prioritize and focus on improving food safety. In 2011, the CDC estimated that each year, 48 million Americans get sick, 128,000 are hospitalized, and 3,000 die from foodborne illness.[7] It is unclear if the increase in authority and requirements have led to a reduction in the rate of foodborne illness in the U.S.[8]

In September 2021 and January 2022, the FDA received reports of cases of illness and death among infants who consumed powdered infant formula from a common manufacturer.[9] After the FDA fielded whistleblower reports, conducted inspections, and issued a consumer advisory,[10] the manufacturer initiated a voluntary recall of the affected products.[11] The FDA faced criticism for its delayed response to the reports and a general lack of communication and engagement across the agency, as well as the supply chain issues that followed.[12]

In January 2023, the FDA announced it would propose a unified Human Foods Program and reorganize its field operations in place of the existing structure.[13] The reorganization, set to begin October 1, 2024, consolidates the functions of the Center for Food Safety and Applied

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[5] U.S. Food & Drug Administration, "FDA at a Glance," 2020, https://www fda.gov/media/143704/download#:~:text=FDA%20regulates%20about%2078%20percent,poultry%2C%20and%20some%20egg%20products.&text=There%20are%20over%2020%2C000%20prescription%20drug%20products%20approved%20for%20marketing.&text=FDA%20oversees%20over%206%2C500%20different%20medical%20device%20product%20categories.

[6] Congressional Research Service, "The Federal Food Safety Program", *RS22600,* 2016, https://crsreports.congress.gov/product/pdf/RS/RS22600/52.

[7] Scallan E, Hoekstra RM, Angulo FJ, et al., "Foodborne Illness Acquired in the United States—Major Pathogens," Emerging Infectious Diseases, 2011, https://wwwnc.cdc.gov/eid/article/17/1/P1-1101_article#;.

[8] Williams, Richard A., and Tyler Richards, "More FDA Spending Does Not Necessarily Mean Better Results," *Mercatus Center*, 2015, https://www mercatus.org/research/data-visualizations/more-fda-spending-does-not-necessarily-mean-better-results.

[9] U.S. Food & Drug Administration, "FDA Evaluation of Infant Formula Response," 2022, https://www fda.gov/media/161689/download.

[10] U.S. Food & Drug Administration, "Timeline of infant formula related activities," 2022, https://www fda.gov/media/158737/download.

[11] U.S. Food & Drug Administration, "FDA Investigation of Cronobacter Infections: Powdered Infant Formula," 2022, https://www fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-infections-powdered-infant-formula-february-2022.

[12] Regan-Udall Foundation for the FDA, "Operational Evaluation of the FDA Human Foods Program," 2022, https://reaganudall.org/sites/default/files/2022-12/Human%20Foods%20Program%20Independent%20Expert%20Panel%20Final%20Report%20120622.pdf.

[13] U.S. Food & Drug Administration, "FDA Modernization Efforts for Establishing a Unified Human Foods Program, New Model for Field Operations and More," 2024, https://www fda.gov/about-fda/fda-organization/fda-modernization-efforts-establishing-unified-human-foods-program-new-model-field-operations-and.

Nutrition, the Office of Food Policy and Response (OFPR), as well as key functions from the Office of Regulatory Affairs (ORA) under one program.[14] The Office of Critical Foods, required by Congress in response to the infant formula crisis, is within the Nutrition Center of Excellence.[15]

The Fiscal Year (FY) 2025 President's Budget request for the Foods Program is $1,258,987,000, of which $1,246,745,000 would be budget authority and $12,242,000 would be from user fees.[16] The budget request would increase by $50,648,000 compared to the FY 2023 Final Level; user fees increase by $475,000. The amount in the request for the Center for Food Safety and Applied Nutrition (CFSAN) is $435,497,000.

Center for Tobacco Products

The FDA is responsible for regulating the manufacture, marketing, distribution, and sale of tobacco products in its Center for Tobacco Products (CTP). This authority was established under the Family Smoking Prevention and Tobacco Control Act of 2009. The CTP's original jurisdiction was limited to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco (e.g., snuff, chewing tobacco). However, the FDA could issue rulemaking to "deem" other tobacco products and therefore subject those products to FDA regulation. In 2016, pursuant to this authority, the FDA promulgated regulations (known as "the deeming rule") that extended the FDA's authority over all tobacco products that were not already subject to the Federal Food, Drug, and Cosmetic Act (FFDCA), such as electronic nicotine delivery systems, or ENDS (an umbrella term for various types of electronic tobacco products, including electronic cigarettes or "e-cigarettes"). The Consolidated Appropriations Act (CAA) of 2022 formally amended the term "tobacco product" to include products containing "nicotine from any source."

The FDA has four different premarket review pathways to facilitate tobacco product commercialization: (1) premarket tobacco application (PMTA), (2) substantial equivalence (SE), (3) exemption from substantial equivalence (EX REQ), (4) modified risk tobacco product (MRTP). To legally market a new tobacco product, a manufacturer must receive a PMTA. A PMTA is not necessary if the FDA determines that the new tobacco product is substantially equivalent (SE) to a predicate tobacco product. For new tobacco products to receive authorization from FDA, the products must be determined to be "appropriate for the protection of public health." To legally market a new tobacco product with reduced risk claims or modify a legally marked tobacco product to make reduced risk claims, a manufacturer must receive an MRTP order.

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[14] U.S. Food & Drug Administration, "FDA's Reorganization Approved for Establishing Unified Human Foods Program, New Model for Field Operations and Other Modernization Efforts," 2024, https://www.fda.gov/news-events/press-announcements/fdas-reorganization-approved-establishing-unified-human-foods-program-new-model-field-operations-and.

[15] U.S. Food & Drug Administration, "Approved Human Foods Program Organization Chart," 2024, https://www fda.gov/media/172384/download.

[16] U.S. Food & Drug Administration, "Department of Health and Human Services Fiscal Year 2025: Food and Drug Administration Justification of Estimates for Appropriations Committees," 2024, https://www fda.gov/media/176925/download?attachment.

The FY 2025 President's Budget request for the Tobacco Program is $798,588,000, made up entirely of user fees.[17] $775,891,000 would be for the Center for Tobacco Products. This is an increase of $121,423,000 above the FY 2023 Final Level. The Budget also requests an additional $121.4 million in user fees. This request includes a program increase of $114.2 million in user fee authority to include manufacturers and importers of all products subject to Chapter IX of the FFDCA for which the FDA assesses tobacco user fees.

Reagan-Udall Reports

On July 19, 2022, FDA Commissioner Califf requested a comprehensive evaluation of the Human Foods Program, including the OFPR, CFSAN, relevant parts of the ORA, and the CTP.[18] He tasked the Reagan-Udall Foundation to collaborate with an external group of experts to perform the evaluations.

One evaluation addressed the CTPs' programs for regulations and guidance, application review, compliance and enforcement, and communication with the public and other stakeholders. The other evaluation focused on structure, function, funding, leadership, culture, and inspectional activities related to the Human Foods Program. Both evaluations yielded a report with operational recommendations for improvement to the FDA in December of 2022.[19] The FDA is currently in the process of addressing and implementing these recommendations.[20]

III. Legislation

H.R. 1462, Defending Against Imitations and Replacements of Yogurt, Milk, and Cheese To Promote Regular Intake of Dairy Everyday (DAIRY PRIDE) Act (Reps. Joyce, Craig and Kuster)

This legislation would prohibit the sale of any food that uses the market name of a dairy product (such as milk, yogurt, or cream cheese) unless the food (1) is the milk of a hooved animal, (2) is derived from such milk, or (3) contains such milk as a primary ingredient.

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[17] *Id.*
[18] U.S. Food & Drug Administration, "FDA Conducting Evaluation of Key Agency Activities to Strengthen Operations," 2022, *Pagefreezer,* https://public4.pagefreezer.com/browse/FDA/20-07-2022T09:13/https://www fda.gov/news-events/press-announcements/fda-conducting-evaluation-key-agency-activities-strengthen-operations.
[19] Regan-Udall Foundation for the FDA, "Operational Evaluation of FDA's Human Foods & Tobacco Programs," https://reaganudall.org/programs/operational-evaluation-fdas-human-foods-tobacco-programs.
[20] U.S. Food & Drug Administration, "Actions to Address Recommendations from the Reagan-Udall Evaluation of CTP," https://www fda.gov/tobacco-products/about-center-tobacco-products-ctp/actions-address-recommendations-reagan-udall-evaluation-ctp; "FDA Advances Reorganization Proposal for Unified Human Foods Program, Field Operations and Additional Modernization Efforts," 2023, https://www.fda.gov/news-events/press-announcements/fda-advances-reorganization-proposal-unified-human-foods-program-field-operations-and-additional.

H.R. 1750, Defending Domestic Orange Juice Production Act of 2023 (Reps. Franklin, Bilirakis, Cammack, Castor, and Soto)

This legislation would require finished pasteurized orange juice to contain at least 10 percent by weight of orange juice soluble solids (currently 10.5 percent), exclusive of the solids of any added optional sweetening ingredients.

H.R. 1803, Codifying Useful Regulatory Definitions (CURD) Act (Reps. Steil and Craig)

This legislation would establish a statutory definition for "natural cheese" as cheese (ripened or unripened soft, semi-soft, or hard) that is produced from animal milk or certain dairy ingredients and is produced in accordance with established cheese-making standards. The definition excludes pasteurized process cheeses, cheese foods, and cheese spreads.

H.R. 2901, Food Labeling Modernization Act of 2023 (Rep. Pallone)

This legislation would update front-of-package food labeling requirements to highlight certain nutritional information, require updates to the ingredient list on packaged food, and impose certain restrictions on how food can be labeled.

H.R. 4547, Laws Ensuring Safe Shrimp Act (Reps. Graves and Castor)

This legislation would provide funding to the FDA and the Department of Agriculture to inspect imported shrimp and shrimp products in accordance with certain health and safety standards and encourage domestic consumption of shrimp.

H.R. 4764, The Honey Identification Verification and Enforcement (HIVE) Act (Rep. Armstrong)

This legislation would require the FDA to establish a standard of identity for honey and report to Congress on enforcement actions taken with respect to adulterated or misbranded honey.

H.R. 6512, Stephen Hacala Poppy Seed Safety Act (Rep. Womack)

This legislation would prohibit the sale of food that is, or contains, unsafe levels of morphine, codeine, or other alkaloid compounds in poppy seeds.

H.R. 6770, Improving Newborns' Food and Nutrition Testing Safety (INFANTS) Act of 2023 (Reps. Sykes, Pallone, and Cárdenas)

This legislation would require food facilities that manufacture or process food for infants and toddlers to test food samples for toxins such as lead, cadmium, mercury, and arsenic. The bill would also require manufacturers of powdered infant formula to implement an environmental monitoring program for Cronobacter spp. and Salmonella. Manufactures would be required to report any contamination to the FDA within 24 hours of discovery.

H.R. 7563, Food Traceability Enhancement Act (Rep. Franklin)

This legislation would require the FDA to conduct pilot projects with restaurants, retail food establishments, and warehouses on the effectiveness and use of traceability lot codes before the compliance date of the "Requirements for Additional Traceability Records for Certain Foods" final rule.

H.R. 9425, Tobacco User Fee Modernization Act of 2024 (Rep. McClellan)

This legislation would increase the amount of fees collected by CTP and increase the amount by inflation in perpetuity. It also requires additional data to be submitted the FDA and authorizes tobacco user fee assessments for all regulated tobacco products, including "deemed" products.

H.R. 9443, Federal and State Food Safety Information Sharing Act of 2024 (Rep. Ross)

This legislation would authorize the Secretary of Health and Human Services to share unredacted information related to foodborne illness surveillance, laboratory sampling testing information, inspection information, distribution lists, consumer complaints, and any other information the Secretary determines will assist in protecting the public with state, local, tribal, and territorial authorities.

IV. Staff Contacts

If you have questions regarding this hearing, please contact Emma Schultheis of the Committee on Energy and Commerce Majority staff at 202-225-3641.