October 7, 2022

Jane Henney, M.D.
Chair
Reagan-Udall Foundation FDA Operational Evaluation
Submitted Electronically

Dear Dr. Henney:

Consumer Brands Association appreciates the opportunity to submit comments to the Reagan-Udall Foundation as part of its evaluation of FDA's Human Foods and Nutrition Program. As we look to the future of our industry, modernizing and reforming FDA is top of mind for the food, beverage and personal care companies we represent. We are hopeful that your work can begin a process to elevate and strengthen FDA's role in supporting the consumer packaged goods (CPG) industry in meeting consumer demands and expectations and innovating for enhanced safety and environmental quality in the decades ahead.

Consumer Brands champions the industry whose products Americans depend on every day, representing more than 2,000 iconic brands. From cleaning and personal care to food and beverage products, the CPG industry plays a vital role in powering the U.S. economy, contributing $2 trillion to U.S. GDP and supporting more than 20 million American jobs.

Our members' experiences across the CPG industry provide real world evidence of why a modernized FDA is warranted. Companies are halting innovation in food packaging and novel foods because of delays in FDA's review of industry submissions. We hear concerns about an inability to innovate, grow and thrive because FDA lacks streamlined decision making for the range of products within its jurisdiction. To meet consumers where they are today, FDA rightly should be modernized to keep pace with consumer demand and preference.

Addressing structural and governance issues at the agency, particularly with respect to FDA's food and nutrition program, is foundational to modernizing FDA in this space. The aggressive modernization of FDA's medical products programs that took place several years ago should serve as model and imperative for FDA's food program to keep pace with industry innovation and consumer demands. But that is just the beginning. Modernization of FDA policies, procedures and IT infrastructure are needed to promote timely agency decision making and assure it can grow and thrive. Taken together, these efforts stand to bolster consumer access to a wide variety of CPG products and provide information to make informed choices.

Unifying FDA's Food Program Under a Deputy Commissioner for Foods

The CPG industry depends on FDA to perform its regulatory role effectively, efficiently and transparently. We appreciate FDA's past collaboration with our industry, consumer groups and the states in implementing the Food Safety Modernization Act (FSMA) and executing on the New Era of Smarter Food Safety initiative. Unfortunately, problems in the food program's organizational structure, governance and performance are impacting the effectiveness of that relationship. Specifically, the lack of a single, full-time, fully empowered, expert leader affects all aspects of FDA's food program. Inefficient decision making has slowed reviews, hindering

progress and even rendering innovation obsolete. Inexperienced and undertrained inspectors are being sent into the field. A split and siloed food program undercuts communication and collaboration at the expense of efficiency and responsiveness. Each of FDA's major food program units, the Office of Food Policy and Response (OFPR), Center for Food Safety and Applied Nutrition (CFSAN), Center for Veterinary Medicine (CVM) and the foods-related components of the Office of Regulatory Affairs (ORA), stands to benefit from a common strategic direction, clear priorities, sound resource management and internal accountability that could result from unifying the program under an expert leader who is accountable and responsible for the program.

Consumer Brands is calling on FDA to unify its food program under a deputy commissioner for foods, with accountability to the commissioner and direct line authority over CFSAN, CVM and the food-related components and operations of ORA. There is an urgent need for this change to be made, and the deputy commissioner should have relevant and appropriate food credentials to quickly implement modifications that will benefit consumers and our industry. A unified structure and a full-time senior leader for the program translate into results we all care about — focused leadership, accountability, timely decision making and effective dialogue with myriad stakeholders. We believe that the ultimate success of FSMA, as well as execution of the New Era of Smarter Food Safety blueprint, requires transparency and robust engagement with industry, consumer groups, state associations and other stakeholders. This is lacking under the current structure and governance model.

Consumer Brands acknowledges that FDA's food and nutrition program may require increased funding to fulfill its mission. Industry advocated for, and FDA received, a budget increase of millions of dollars to implement FSMA. A full accounting of those resources is needed before we can advocate for additional funding. Following that, a review and realignment around strategic program priorities could help FDA, and its stakeholders, make the case for bolstering funding if needed.

Modernizing the Agency

Organizing under a deputy commissioner for food is step one, not the only step. FDA must develop and implement a structured, prioritized regulatory agenda for its foods program, utilizing a transparent process that allows for stakeholder input and includes a public process for rulemaking and issuance of guidance.

Consumer Brands is working with member companies to define a series of high value, product-related policies that embrace technological advancements and reframe FDA's food program operations. A decade ago, we would have thought about modernizing FDA to move at the speed of business. Years later, it is essential that FDA is reformed to move at the speed of the consumer, meeting their rapidly changing preferences and demands.

To date, the major categories identified for modernization are as follows:

- Inspection Modernization: Move from one size fits all inspections to a tailored, risk-based inspection model and facilitate an integrated federal-state approach to regulatory oversight to assure consumers have access to safe food.

- Recall Modernization: Harmonize government recall policies and processes and modernize communications and modes of delivery of those communications to assure consumers do not get sick from recalled food products.

- Labeling Modernization: Update labeling policies to embrace the use of digital technology to convey product information to consumers and account for the increased use of ecommerce by consumers for purchasing food products.

- Industry Submission Modernization: Embrace the use of technology and novel risk prioritization and assessment models to streamline the review of industry submissions, facilitating packaging and product innovation and consumer access to novel foods.

- Novel Foods: Ensure more timely agency decisions on the safety and labeling of novel foods and food ingredients to enhance consumers' access to a wide variety of products.

- New FDA-Industry Collaborative Models: Lead efforts to formalize private-public models to expeditiously create and post in the public domain just-in-time industry best practice documents, as was done during the pandemic, to assure consumers have access to products they use in their homes every day.

- Consumer Transparency and Traceability: Partner with government to develop implementation plans for the food traceability rule and other end-to-end product visibility initiatives to provide consumers with the information they demand on CPG products and assist with quickly removing products from the marketplace, when needed.

- Prioritization and Risk Assessment for Chemical Contaminants: Develop a transparent regulatory agenda for chemical contaminants in packaging and products to provide certainty to industry and consumer access to safe foods.

- Integration with Commitments on Sustainability: Position FDA as a leader and subject matter expert in facilitating food packaging innovation to assist industry in meeting state-mandates for recycled content and packaging material bans and address consumer demand for companies to be environmentally responsible.

- IT Infrastructure Modernization: Enable FDA to collate and mine big data to inform policy, make decisions and more responsibly use resources provided through Congress to ultimately assure consumers have access to a wide variety of safe foods.

Such reforms stand to position FDA as a leader and subject matter expert in facilitating innovation, assisting industry in meeting state mandates on issues related to packaging materials and enabling data to drive decision making.

There also is opportunity to apply lessons learned from the COVID-19 crisis. The pandemic created unprecedented challenges for the CPG industry, demanding new approaches to manufacturing processes and temporary changes to government policies and regulations. The use of enforcement discretion to provide companies with labeling flexibilities; new models to produce just-in-time guidance for industry; and modernized inspection models including remote regulatory assessments, allowed CPG companies to focus on and continue to make safe products for consumers during the pandemic. Many of these crisis-driven actions have proven as safe and more efficient at achieving the goals of pre-crisis public policy and should be made permanent. The experience of the pandemic demonstrates that regulators like FDA and industry can work together to improve the regulatory environment.

Conclusion

The CPG industry is accountable to and responsible for the consumers it serves. Working at the speed of the consumer requires a strong, modernized FDA — one that is structured, governed and funded for success. That may not be the case today, but it is also not the fate of tomorrow if FDA chooses to make smart, needed changes.

Our industry stands ready to respond to and partner with the FDA to meet the essential, daily needs of American families. We believe there is ample opportunity for industry, Congress and the administration to work together and deliver a modernized FDA food program.