To: Cc: Subject: Date: Attachments:



From the Desk of the CFSAN Director



Dear CFSAN Colleagues,

I am writing to let all of you know that I am planning to retire on May 31, after having had the honor and privilege of serving as your Center Director for the past 8.5 years. In reflecting back over this remarkable time, I am immensely proud of and humbled by what we have accomplished together, in so many areas. While our accomplishments have been many, highlights would include:

Food Safety: Since 2015 we have issued 9 FDA Food Safety Modernization Act (FSMA) rules and almost 70 guidances, a massive undertaking to overhaul the U.S. food safety system in a prevention-oriented framework. We continue to advance this approach by establishing a series of <u>prevention strategies</u>, targeting commodities where we have seen repeated food safety issues. This is prevention of foodborne illness at its best. It is therefore perhaps not surprising that the Economist 2022 Global Food Security Index Report recently ranked the U.S. as tied for first in the food safety indicator category out of 113 countries; this ranking reflects all your hard work and dedication.

To address the important issue of chemical food safety, we have taken concrete steps to reduce exposure to toxic elements such as arsenic, lead and mercury in foods targeted for infants and young children. One of my first areas of focus upon arriving at CFSAN was inorganic arsenic in infant rice cereal, with rice cereal being the predominant source of exposure to arsenic for infants. Working as a team we issued draft and <u>final action levels</u>, followed by action levels for lead in juices and in various categories of foods for babies and young children, along with fish advice helping to inform consumers how they can get the nutritional benefits of fish while reducing exposure to mercury. The impact of these actions is already evident; for example, from 2012-2019 inorganic arsenic levels in infant rice cereal decreased by 29%. I look forward to following your continued progress on bringing these levels down further through the path we've charted out in <u>Closer to Zero</u>.

In addition, <u>PFAS chemicals</u> have emerged as a priority food safety issue. To address enormous data gaps, we have taken aggressive steps forward to understand where PFAS contamination of the food supply is occurring, supported states/regions with local contamination of food, and implemented strategies to reduce exposures, including via product recalls and the phase-out of certain PFAS used in food contact. There is much more to be done on PFAS, but we have led with our science and public health values to protect consumers. Our learnings from PFAS and other chemicals of interest are informing our approach to modernize our oversight of chemicals in foods, as we work to build a systematic, transparent, data-driven approach to risk prioritization for chemical reassessment.

One last example—taking action on asbestos contamination of <u>talc</u> in cosmetic products. We used a "whole of government" approach to evaluate analytical methods to assess asbestos contamination in talc-containing cosmetic

products, and then took regulatory action following sampling to remove contaminated products from the market and protect public health.

Nutrition: Nutrition policies put in place over the last 8+ years are arguably some of the most impactful ever to come out of FDA. Eliminating artificially produced *trans* fats, also known as partially hydrogenated oils, is estimated to prevent tens of thousands of cardiovascular disease events each year in the U.S., and our work on sodium reduction across the U.S. food supply has the potential to prevent hundreds of thousands of premature deaths and illnesses in the coming years. The World Health Organization (WHO) is working to emulate our policies on *trans* fat and sodium reduction across the globe.

We have used FDA labeling authorities to empower consumers to make healthier choices, including mandating added sugars on the Nutrition Facts label for the first time, and implementing menu labeling, providing much-needed calorie and nutrition information given that consumers typically eat a third of their daily calories away from home. Recent labeling actions, such as the updated definition of "healthy" which was proposed in 2022, and the work underway on front-of-pack nutrition labeling, are signature initiatives in the White House National Strategy on Hunger, Nutrition, and Health, that will further empower consumers.

Advancing science and fostering innovation: By 2015, whole genome sequencing (WGS) for foodborne pathogens was becoming more common and just beginning to have positive impacts on outbreak response. For example, CDC reported WGS resulted in more outbreaks solved for *Listeria* with fewer numbers of cases from 2013-2016. Today, WGS is arguably the most important and impactful scientific development transforming microbial food safety and the GenomeTrakr network is changing the face of food safety globally. While we have been focused in on pathogens such as *Listeria*, *Salmonella*, and *E. coli*, we have been expanding beyond bacterial pathogens to develop analytical methods for parasites (*Cyclospora*), and viruses (norovirus, hepatitis A virus).

Our scientific reviewers have supported the rapidly expanding innovation in foods while assuring food safety — for example by completing first ever consultations for cell-cultured foods, and genome edited plants. New food technologies such as genome editing are potentially important tools to fight climate change and enable agriculture to feed the world's growing population.

Organizational Efforts: In 2015, fully half of the Center Leadership Team was in acting roles as they worked to onboard a new Center Director. To build a more permanent and empowered leadership team, we recruited from within CFSAN, from other parts of FDA, and externally to build an experienced, dedicated, and passionate leadership team. Organizational change in the former Office of Foods and Veterinary Medicine brought new components into CFSAN, including the Coordinated Outbreak Response and Evaluation (CORE) Network, which now has closer alignment with our Offices of Compliance and Food Safety. CORE continues to advance outbreak response and public transparency around outbreaks and has emerged as the model for outbreak response. As part of that organizational change, we built our Office of Executive Programs, that has coordinated, project-managed and advanced our daily work. We also brought communications and public engagement staff into CFSAN, resulting in closer partnerships between communications experts and subject matter experts.

We strengthened our Office of Management, including our budget group that has received three times as many FDA awards for excellence in financial management as the next best FDA center budget group over the past three years. Excellence in budgetary formulation was also foundational to our receipt of \$32 million in new appropriated dollars for CFSAN in FY23 and the largest request ever for total CFSAN funding (a requested increase of \$106.7 million) in the FY24 President's budget.

We have built a culture founded on strong science, respect for others, and increasing transparency, resulting in increased employee engagement, with year after year improvements in Federal Employee Viewpoint Survey (FEVS) measures including employee participation, engagement, and global satisfaction. Our People Committee and our Diversity, Equity, Inclusion, and Accessibility (DEIA) Council, implemented in 2014 and 2020 respectively, are changing and will continue to change our culture and composition, supporting recruitment and retention of a highly diverse, talented, and specialized workforce.

Unexpected Challenges: From a 35-day government shutdown to the COVID-19 pandemic, to infant formula shortages, we demonstrated time and again our collective resilience. We were inspired by actions taken by our colleagues during COVID-19, including numerous deployments of our Commissioned Corps officers, recognized in our CFSAN heroes' communications. In response to infant formula shortages, we addressed unprecedented challenges, we applied creative

solutions and set new records for rapidity in obtaining a consent decree and created a new pathway and issued guidance in record time for regulatory flexibility to allow new products to come into the market, supporting the supply chain. We have doubled the number of manufacturers bringing products into the U.S. market, while also focusing on the safety of powdered infant formula through our prevention strategy. The result of these efforts, along with manufacturers increasing production, is that in-stock rates (currently at 89%) are back to where they were before the February 2022 recall. Working through these and other challenges, our teams have emerged stronger and better prepared for future challenges.

Setting the Stage for the Future: As noted earlier, this year we received crucial new resources, but also critically important new hiring authority under Title 21, and authorities to modernize oversight of cosmetics that we have fought so hard for, demonstrating the power of persistence.

Human Foods Program Reorganization: While the Center has evolved to a new level of performance and delivery over the past 8 years, it was necessary that FDA look critically at the broader foods program structure, to reduce redundant operations, increase efficiencies, and make optimal utilization of our field resources. The Commissioner's proposal will address these issues, enabling the transition to an even better Human Foods Program for the future, which I strongly support.

As we enter this new phase, I have decided that it is time for me to pass the leadership baton to a new generation of leadership who can commit to implementing the Commissioner's vision in the coming years. I am proud to have been one of the longest serving, and only female, CFSAN Center Directors. I have been eligible to retire since 2021, and my spouse recently retired (2022), so I am looking forward to joining him in retirement. I have loved my 27 years in academia at Yale School of Public Health, followed by my 8+ years in leadership at FDA. Without a doubt, I view my time at the FDA as the culmination of my professional journey – both for impact and having gotten to know and work with the most dedicated and talented public servants possible.

Best, Susan

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