

January 25, 2023

Dr. Robert Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dr. Califf:

This letter is to inform you that I am resigning my position as FDA Deputy Commissioner for Food Policy and Response effective February 24.

In December of 2018, I joined the FDA with the goal of helping to modernize the food safety oversight system in the United States and protecting the American people from contaminated food. I wanted to build on my work of protecting consumers by elevating food safety standards and building more effective, modern, and innovative food safety approaches, something I did in the private sector for more than 30 years.

Despite the unprecedented challenges we've faced in the past four years (such as a global pandemic, unparalleled food supply chain disruptions, and six different acting or permanent commissioners), thanks to the dedicated staff working on food safety throughout the FDA, I believe we made real improvements towards this goal.

Advancing FSMA

First, almost a decade since its passage and after the agency experienced three separate lawsuits (before my arrival) for failing to achieve several Food Safety Modernization Act (FSMA) mandates, we made needed and strategic progress by tackling two of the most critical, complicated, and outstanding FSMA rulemakings by issuing a [Final Food Traceability Rule](#) and a new, [proposed Agricultural Water Standard](#). While the FSMA-projected reductions in foodborne illnesses have yet to be realized a decade later, these two rules, once fully implemented, will be gamechangers in allowing those reductions to become a reality.

A New Era of Smarter Food Safety

But we didn't stop there. Modern times require more modern approaches. Therefore, shortly after my arrival, we assembled some of the brightest minds in food safety from within and outside the FDA to help us prepare for the future. Based on their input, in 2020 and under the auspices of a [New Era of Smarter Food Safety](#), we unveiled a new vision and blueprint for the next decade to modernize the way FDA does its food safety work and to bend the curve of foodborne illness once and for all in this country. And in two short years, we achieved an amazing amount of work. For example, we leveraged smarter tools for prevention used for the very first time in FDA's food program, such as employing [Artificial Intelligence](#) to strengthen our ability to detect and prevent violative shipments of imported seafood from reaching the U.S. consumer. We also expedited and facilitated the use of [Tech-enabled Food Traceability](#) to create a more transparent food system. And at a time of heightened food supply chain disruptions, we unleashed the power of data with the

development of [21 Forward](#), a first of its kind food supply chain analytical platform to identify food facilities at greatest risk of food supply chain disruptions. We also launched a pilot to evaluate if select [third party food safety standards](#) aligned with FSMA and determine what role they might play in the nation's food safety oversight system. And we advanced the concept of [Food Safety Culture](#) to achieve higher rates of compliance and to mobilize industry to do the same, realizing that advancing food safety requires going beyond traditional approaches, through a better understanding of human behavior and organizational dynamics.

A Record of Prevention

Importantly, while regulatory activities matter, they're not what matters most. What matters most is outcomes or proven results that our work is achieving reductions in foodborne illnesses. And early indications are that we've been successful here too, whether it's been through our work to rally stakeholders to break the cycle of recurring outbreaks around Thanksgiving linked to fresh leafy greens through FDA's [Leafy Green Action Plan](#) or, after 8 years and 8 outbreaks, breaking the cycle of Salmonellosis during the summer linked to [imported papayas](#), through an [enhanced Food Safety Partnership](#) between the U.S. and Mexico, as just a couple of examples.

Tackling Foodborne Outbreaks Faster

And while prevention has been and must always be our focus, tackling foodborne outbreaks faster and revealing their root cause is also essential to preventing future outbreaks, so here too, we made significant progress. For example, we strengthened FDA's foodborne outbreak investigations and almost doubled the number of outbreak investigation reports the agency now publishes. Also, as a commitment to greater transparency, we began a process of sharing information about the outbreaks the FDA is investigating through a [weekly outbreak update table](#), even before there is any actionable information. And importantly, we completed an independent review of our outbreak investigation processes that led to the development of a [Foodborne Outbreak Response Improvement Plan](#).

I want to THANK all of those in the FDA who have committed themselves to these efforts and I hope that they are given the opportunity to continue this important work in the future. I hold the food safety staff throughout the agency in the highest regard, for their expertise, their experience, and – most of all - their commitment to the public.

Looking to the Future

In February 2022, as you rejoined the agency, I shared with you that I was considering leaving, expressing my concern that the decentralized structure of the foods program that you and I both inherited, significantly impaired FDA's ability to operate as an integrated food team and protect the public.

It was also in February of 2022 that I first learned of the infant formula incidents that had been reported to various parts of the FDA several months before, so I postponed this decision and dedicated myself and my staff to doing all we could to help tackle this crisis. With the Abbott facility now reopened, infant formula availability more prevalent, and – very importantly - the necessary monitoring, data systems, and insights now in place through the 21 Forward platform to help

address the current and any future infant formula supply chain challenges, I believe the time is right for me to leave and vacate this position.

My fervent hope is that American consumers, especially mothers and fathers of infants, never again have to face this type of preventable situation. It is incumbent on any public organization that has undergone a crisis of this magnitude to undergo an independent and thorough review to understand how the crisis happened, what can be done to prevent it from happening again, and that the findings be transparently shared with the public. I am grateful that Congressional leaders have demanded that this happen and that the Office of the Inspector General has initiated its own investigation.

Lastly, while I respect that these are decisions only you can make, I do want to leave you with a couple of points for consideration. One, based on my experience these past four years, I (as well as a diverse group of [Bipartisan Congressional Leaders](#) and [Consumer, State Regulatory, & Industry Stakeholder Groups](#)) firmly believe the agency would operate more effectively and be better able to protect the American public from foodborne illness, with the creation of a more integrated operating structure and a fully empowered and experienced Deputy Commissioner for Foods, with direct oversight of those centers and offices responsible for human and animal foods. In this manner, she or he can more easily make the necessary changes that are needed to transform FDA's Food Program for the 21st Century. Secondly, I also urge you to consider transferring the small, yet exceptional staff comprising the Office of Food Policy and Response (OFPR) to a new office of the Deputy Commissioner for Foods.

In closing, I will always remain grateful for the opportunity to have served our one and only true boss, the approximate 340 million American consumers nationwide. Serving them has been a honor and privilege.

A handwritten signature in black ink, appearing to read 'Frank Yiannas', with a long horizontal flourish extending to the right.

Frank Yiannas
Deputy Commissioner, Food Policy and Response