

ONE HUNDRED SEVENTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
COMMITTEE ON ENERGY AND COMMERCE  
2125 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-6115

Majority (202) 225-2927  
Minority (202) 225-3641

July 12, 2022

The Honorable Robert Califf, M.D.  
Commissioner of Food and Drugs  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Dear Commissioner Califf:

We write with urgency as the nation's infant formula shortage continues and new foodborne illness threats emerge to request your plan for strengthening the Food and Drug Administration's (FDA) food safety efforts. The Committee has long held concerns regarding FDA's food safety inspection and coordination activities. As recently discussed with FDA, current events surrounding the infant formula recall and shortage have further amplified questions about the agency's execution of its responsibilities to ensure food safety in the United States. During a May 25, 2022, Oversight and Investigations Subcommittee hearing, you testified that you "did not return to the FDA to preside over business as usual" and that you "will be looking at the overall food program from the perspective of reforming it."<sup>1</sup> We are encouraged by this statement but seek further details and a timeline as the nation continues to face food safety and supply challenges.

Over the past two months, reports of bacterial or viral contamination of common foods, such as peanut butter, strawberries, peaches, and cheese, demonstrate the urgency to reinvigorate FDA's food program.<sup>2</sup> Since May 2, 2022, there have been 16 reported illnesses in 12 states, two of which led to hospitalization, due to possible *Salmonella* contamination in certain brands of Jif peanut butter.<sup>3</sup> On May 20, 2022, the J.M. Smucker Company issued a voluntary recall of

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<sup>1</sup> House Committee on Energy and Commerce, *Hearing on Formula Safety and Supply: Protecting the Health of America's Babies*, 117<sup>th</sup> Cong. (May 25, 2022).

<sup>2</sup> *Several Jif Peanut Butter Products Recalled Over Potential Salmonella*, New York Times (May 23, 2022); *Hepatitis A Outbreak in U.S. and Canada Linked to Strawberries*, New York Times (May 31, 2022).

<sup>3</sup> Food and Drug Administration, *Outbreak Investigation of Salmonella: Peanut Butter (May 2022)* ([www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-salmonella-peanut-butter-may-2022?utm\\_medium=email&utm\\_source=govdelivery](https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-salmonella-peanut-butter-may-2022?utm_medium=email&utm_source=govdelivery)) (accessed July 8, 2022).

select Jif products, which has since triggered 20 additional recalls by companies that use Jif as a supplier.<sup>4</sup> FDA's investigation found a match between the strain of *Salmonella* causing illnesses in the current outbreak to a strain found in an environmental sample collected in 2010 from the Lexington, Kentucky plant that produces Jif peanut butter.<sup>5</sup> Yet, the last FDA inspection of this plant was conducted over four years ago, in February 2018, during which inspectors did not observe any objectionable conditions or practices.<sup>6</sup>

In May 2022, FDA announced that it was investigating a multistate outbreak of hepatitis A infections potentially linked to fresh organic strawberries imported from Mexico by a common supplier.<sup>7</sup> The strawberries are sold under two brands by nine retailers across the country, including Walmart, Kroger, Safeway, and Trader Joe's. As of June 23, 2022, 18 cases of infection have been reported, with 13 resulting in hospitalization. And, on May 25, 2022, Brookshire Grocery Company voluntarily recalled bulk yellow flesh peaches imported from Chile due to possible *Listeria monocytogenes* contamination.<sup>8</sup> Further, on June 1, 2022, Paris Brothers, Inc. voluntarily recalled eight cheese products distributed to grocery stores in nine states also due to possible *Listeria monocytogenes* contamination.<sup>9</sup> Fortunately, no illnesses have been reported in either case of *Listeria monocytogenes* contamination, as the recalls were a result of sampling conducted by the Texas Department of Health Services and FDA, respectively—instances of food safety efforts working to protect Americans' health.

Foodborne illness in the United States is a common and costly public health challenge, sickening about 48 million people—roughly one in six Americans—hospitalizing 128,000, and killing 3,000 each year.<sup>10</sup> The very young, the elderly, and people with weakened immune systems are at greater risk of serious consequences from most foodborne illnesses.<sup>11</sup> FDA's responsibility to ensure the safety of approximately 80 percent of the food supply, including

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<sup>4</sup> Food and Drug Administration, *The J. M. Smucker Co. Issues Voluntary Recall of Select Jif® Products Sold in the U.S. for Potential Salmonella Contamination* (May 20, 2022) (press release); Food and Drug Administration, *2022 Recalls of Food Products Associated with Peanut Butter from J.M. Smucker Company due to the Potential Risk of Salmonella* ([www.fda.gov/safety/major-product-recalls/2022-recalls-food-products-associated-peanut-butter-jm-smucker-company-due-potential-risk-salmonella](http://www.fda.gov/safety/major-product-recalls/2022-recalls-food-products-associated-peanut-butter-jm-smucker-company-due-potential-risk-salmonella)) (accessed July 8, 2022).

<sup>5</sup> See note 3.

<sup>6</sup> Food and Drug Administration, *Inspections* (<https://datadashboard.fda.gov/ora/cd/inspections.htm>) (accessed July 8, 2022).

<sup>7</sup> Food and Drug Administration, *Outbreak Investigation of Hepatitis A Virus: Strawberries (May 2022)* ([www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-hepatitis-virus-strawberries-may-2022](http://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-hepatitis-virus-strawberries-may-2022)) (accessed July 8, 2022).

<sup>8</sup> Food and Drug Administration, *Brookshire Grocery Company Recalls Yellow Flesh Peaches Because of Possible Health Risk* (May 25, 2022) (press release).

<sup>9</sup> Food and Drug Administration, *Paris Brothers Inc. Voluntary Limited Recall* (June 1, 2022) (press release).

<sup>10</sup> Government Accountability Office, *Food Safety: A National Strategy Is Needed to Address Fragmentation in Federal Oversight* (Jan. 2017) (GAO-17-74).

<sup>11</sup> Food and Drug Administration, *What You Need to Know about Foodborne Illnesses* ([www.fda.gov/food/consumers/what-you-need-know-about-foodborne-illnesses](http://www.fda.gov/food/consumers/what-you-need-know-about-foodborne-illnesses)) (accessed July 8, 2022).

virtually all foods other than meat, poultry, processed egg products, and catfish, and to monitor food manufacturing firms and the foods they produce is paramount to protecting the most vulnerable among us.<sup>12</sup>

Given the need for an effective food program at FDA, we request that FDA provide the Committee with the following information by July 26, 2022.

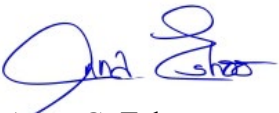
1. The plan for assessing the agency's ability to execute its food safety responsibilities and for implementing reforms necessary to strengthen overall food safety infrastructure and response and close any gaps identified during the assessment. Please detail the specific roles, coordination, and leadership responsibilities of the various office and center staff engaged in any food-related activity.
2. The timeline for implementing the plan and associated assessment.
3. Identify what, if any, additional authorities or resources may be necessary from Congress to implement the plan.

Thank you for addressing this important issue and for your continued leadership. For any questions regarding this request, please contact Stephen Holland and Jesseca Boyer with the majority staff and Kristin Seum and Alan Slobodin with the minority staff.

Sincerely,



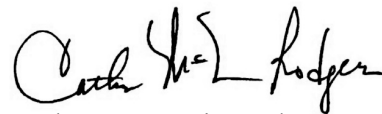
Frank Pallone, Jr.  
Chairman



Anna G. Eshoo  
Chairwoman  
Subcommittee on Health



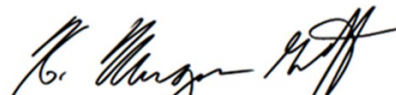
Diana DeGette  
Chair  
Subcommittee on Oversight  
and Investigations



Cathy McMorris Rodgers  
Ranking Member



Brett Guthrie  
Ranking Member  
Subcommittee on Health



H. Morgan Griffith  
Ranking Member  
Subcommittee on Oversight  
and Investigations

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<sup>12</sup> Government Accountability Office, *Food Safety: FDA Continues to Evaluate and Respond to Business Concerns about the Produce Rule* (Nov. 27, 2017) (GAO-18-85).