

2413 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-0703  
(202) 225-3661

59 ELM STREET  
SECOND FLOOR  
NEW HAVEN, CT 06510  
(203) 562-3718

DURHAM / MIDDLEFIELD / MIDDLETOWN  
(860) 344-1159

WEBSITE: [HTTP://DELAWARE.HOUSE.GOV](http://delaware.house.gov)



UNITED STATES  
HOUSE OF REPRESENTATIVES

ROSA L. DeLAURO  
3RD DISTRICT, CONNECTICUT

August 3, 2018

CO-CHAIR, DEMOCRATIC STEERING AND  
POLICY COMMITTEE

COMMITTEE ON APPROPRIATIONS  
SUBCOMMITTEES  
RANKING MEMBER  
LABOR, HEALTH AND HUMAN SERVICES,  
EDUCATION, AND RELATED AGENCIES  
AGRICULTURE, RURAL DEVELOPMENT,  
FOOD AND DRUG ADMINISTRATION,  
AND RELATED AGENCIES

The Honorable Scott Gottlieb, M.D.  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

I write out of concern about the current outbreak of cyclosporiasis as well as the transparency and timeliness of your agency's ongoing investigation.

As of this week, the Centers for Disease Control and Prevention (CDC) has reported a total of 395 infections, across 15 states, in people who consumed Fresh Express supplied salads at McDonald's restaurants. To date, there have been 16 hospitalizations.

Although once rare in the United States, parasitic outbreaks caused by *Cyclospora* have become more common over the last several decades. Many of these outbreaks have continually been found to be associated with imported fruits and vegetables.

Earlier last month, several Midwest state public health departments announced investigations linked to salad consumed at McDonald's. On July 13, 2018, McDonald's announced it would voluntarily stop selling salads at 3,000 of its restaurants until it could procure product from another supplier.

However, it was not until July 26 that the Food and Drug Administration (FDA) completed analysis showing that an unused package of product distributed to McDonald's by the supplier, Fresh Express, was contaminated with *Cyclospora*. Fresh Express was notified of the analysis the following day, and, according to FDA, "Fresh Express committed to using recall procedures to inform those companies that received this romaine about the sample result."

Sometime between July 27 and July 30, Fresh Express notified Caito Foods, LLC that they had received recalled product, prompting the Department of Agriculture's Food Safety and Inspection Service (FSIS) to issue a July 30 public health alert on beef, pork and poultry wraps distributed by Caito Foods.

This timeline of events does not instill confidence that FDA has acted within the best interests of consumers in order to get potentially contaminated product out of the marketplace. As such, I seek specific, written responses to the following questions by September 7, 2018.

1. When did FDA learn that Fresh Express was the supplier of the implicated lettuce blend used in McDonald's salads?
2. To date, what records has FDA requested from Fresh Express related to the ongoing investigation? When were these records originally requested? For records that have been obtained, when did FDA receive them?
3. Did FDA receive a list from Fresh Express containing companies who received potentially contaminated product? Other than McDonald's and Caito Foods, LLC, has any other fast food chain or food distributor received similar, potentially contaminated product from Fresh Express? If so, what is the status of removing this product from the supply chain, and why have those companies not be named in this investigation?
4. Has FDA received any information from Fresh Express that would indicated where the contaminated product was grown and processed? Specifically, was the contaminated product grown in the United States or imported from a foreign country? If the contaminated product was grown and processed in the United States, has FDA (or its state partners) visited and inspected the farms/processing facilities that may currently be implicated?
5. Given that McDonald's and Caito Foods, LLC both received similar, potentially contaminated product from Fresh Express, what explains the 18-day difference between each company's recall? Following statement by McDonald's on July 13, was there any consideration given to notifying and working with other companies that were supplied similar, potentially contaminated product from Fresh Express?

Thank you for your attention, and I look forward to your response.

Sincerely,



Rosa L. DeLauro  
Member of Congress