

Congress of the United States

Washington, DC 20515

June 10, 2016

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

Dear Commissioner Califf,

We are writing in response to an early alert issued today by the Department of Health and Human Service's Inspector General on preliminary findings of an audit of the agency's food recall process. We urge you to work quickly to update the agency's recall policy so that it conducts intensified testing and issues recalls more quickly in order to prevent illnesses and deaths.

The Inspector General's preliminary findings detail two foodborne outbreaks in which the agency did not initiate recalls until 165 days and 85 days after it became aware of a public health risk to consumers linked to a regulated food product. We understand that the agency has issued many voluntary recalls in a timely fashion and is working to update its food safety policies pursuant to the *Food Safety Modernization Act*. These findings are still deeply concerning and we ask that you work swiftly to improve the agency's outbreak investigation and recall processes.

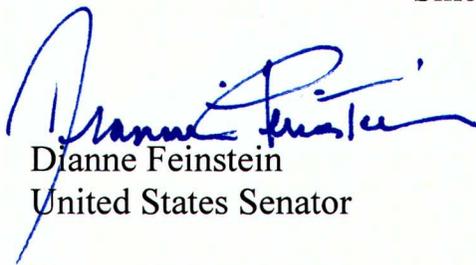
We are also concerned for those instances where the agency did not issue a recall during the course of an outbreak linked to a regulated product. For example, in 2013, 2014, and 2015 there were large multistate *Cyclospora* outbreaks that were linked to cilantro imports from Mexico and similar seasonal and geographic patterns. In total, these outbreaks were linked to 1,481 infections. However, in each of these three outbreaks, no recall was ever issued. Failure to issue any recall puts Americans at risk.

According to the Centers for Disease Control and Prevention's investigation of the 2014 outbreak, your agency did not begin to conduct intensified testing of cilantro imports from Mexico until August, 28, 2014. This is in spite of the fact that the majority of illnesses in this outbreak were reported in June and July. Given the similar 2013 outbreak, it is our view that the agency had justification to being more immediate intensified testing of cilantro in 2014. We appreciate that

the agency has issued an import alert for cilantro produced in a specific region of Mexico to help prevent further outbreaks. However, we ask that you also carefully review how these three outbreak investigations were handled and determined what improvements can be made to the agency's processes.

Thank you for your attention to our request. We look forward to your response.

Sincerely,



Dianne Feinstein
United States Senator



Kirsten Gillibrand
United States Senator



Rosa L. DeLauro
United States Representative

DF/tc