

United States Senate

February 14, 2020

Stephen M. Hahn, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD, 20993

Dear Commissioner Hahn:

I write to request information regarding the Food and Drug Administration's (FDA) recent decision to remove the agency's inspectors of Chinese pharmaceutical manufacturing facilities from the country in response to China's 2019 Novel Coronavirus outbreak.

First, I want to commend you for protecting FDA employees and pulling them out of harm's way. Although there are reports the virus has infected more than 60,000 people globally, I do not trust Communist China to coordinate in a transparent and efficient manner when it comes to combatting the threat of the virus. The United States must do everything in our power to protect Americans and prevent the spread of the virus.

While removing FDA employees from China was the right decision, I write today to ask that you provide answers to the following:

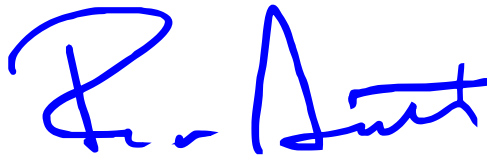
- Are inspections still being conducted?
- Please provide a full list of products that the FDA typically inspects in China.
- FDA facility inspections are typically done for new drugs, or done as part of a risk-based inspection.
 - How many new branded drugs, biologics, generics, vitamins, or medical devices may not be able to enter the marketplace because of the Chinese Coronavirus?
 - How many risk-based inspections will not be carried out because of the current Chinese Coronavirus epidemic?
 - Are these products, or any subset of these products, still being imported into the United States?
 - If so, does the FDA continue to certify that the goods previously inspected in China are still safe for Americans' use and consumption?

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- Should the United States consider suspending these products from being imported into the United States until full inspections can be conducted?
- Given the origin of this outbreak, should the United States consider new, stricter standards for goods imported from China?
- Does the FDA have any estimate on how large the inspection backlog will be if FDA inspectors are out of China for a one month period or longer?
- Does the FDA have sufficient funding to deal with this workload disruption when the Chinese Coronavirus epidemic is contained?

Thank you for your leadership and for your quick attention to this matter. I look forward to hearing from you as we work together to contain infection cases, protect American consumers and stop the spread of the Chinese Coronavirus.

Sincerely,

A handwritten signature in blue ink, appearing to read "Rick Scott". The signature is stylized with a large initial "R" and a prominent "S".

Rick Scott
United States Senator