United States Senate
WASHINGTON, DC 20510-0908

December 13, 2023

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

Dear Commissioner Califf:

We write with regard to the U.S. Food and Drug Administration's (FDA) foreign inspection criteria and process. For decades, Americans have trusted the FDA to ensure that medications and medical devices made abroad are safe to use. However, multiple cases of unsafe and unhygienic foreign products and production facilities call into question whether the FDA is holding foreign manufacturers to the same quality and safety standards it imposes on domestic facilities. Lax and infrequent inspections of foreign facilities threaten patients, while also threatening domestic producers that are held to a higher standard.

Pursuant to section 374(h)(1) of the *Federal Food, Drug, and Cosmetic Act*, drugs manufactured in foreign countries, and intended for use in the United States, must meet the same statutory and regulatory requirements as drugs produced in the United States. This is far from the case today. The *Food, Drug, and Cosmetic Act* requires the FDA to inspect domestic and foreign establishments using a risk-based schedule, weighing how often the agency inspects facilities based on a set of risk factors such as compliance history, the inherent risk of manufacturing the drug or device, and the plant's history of recalled products. Yet, agency data shows that FDA completed only eight inspections of Chinese drug manufacturers and zero of Chinese device manufacturers in 2022. Meanwhile, the FDA completed 897 inspections of domestic drug manufacturers and 1,706 inspections of domestic device manufacturers in 2022. It is of course critical that every drug and device manufacturer, foreign or domestic, receives timely, thorough inspections. But the FDA's inspection records show a clear and perverse disparity. In effect, the FDA is treating American producers as if they are orders of magnitude more risky than foreign producers, when the opposite is plainly true.

Americans are frequently endangered by low quality and unsafe drugs and devices manufactured abroad. Earlier this month, Cardinal Health recalled 32 million of its Chinese syringes due to a manufacturing error that could have caused patients to overdose or underdose. Similarly, valsartan, a drug commonly used for high blood pressure and heart failure, was recalled in 2018 because the manufacturer of the drug's active pharmaceutical ingredient (API) in China changed its manufacturing processes without a formal risk assessment, leading to an impurity suspected of causing cancer to contaminate the drugs. This recall led to more than half of all valsartan products to be pulled from shelves.

Americans deserve to have confidence that the drugs and devices they purchase will improve their health, whether they were produced here or abroad. We must also ensure that foreign manufacturers are held to the same standard as domestic manufacturers to avoid putting our workers and factories at a disadvantage in the global market. It is clear that the FDA is not taking adequate steps to ensure a level playing field for American industry. Therefore, we respectfully request that you provide answers to the following questions:

1. Why were there zero FDA inspections of foreign medical device manufacturers in 2022?
2. How many inspections of foreign drug manufacturers and device manufacturers does the FDA intend to complete in 2023? Planned for 2024?
3. Given the low number of inspections of foreign manufacturers compared to domestic manufacturers, how can the FDA guarantee that drugs and devices manufactured overseas meet the same requirements as those produced in the U.S.? Why should those drugs and devices be allowed to enter our market at all, if they are not held to the exacting standards of American-made drugs and devices?
4. What steps is the FDA taking to increase the number of foreign inspections overall?
5. What would need to change for the FDA to complete a similar number of foreign and domestic inspections?

Thank you for your attention to this matter. We look forward to your prompt response.

Sincerely,

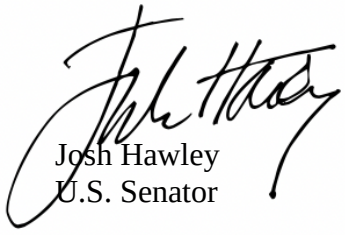
Marco Rubio
U.S. Senator

Cindy Hyde-Smith
U.S. Senator

Marsha Blackburn
U.S. Senator

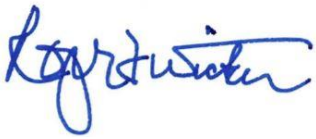
Mike Braun
U.S. Senator

Pete Ricketts
U.S. Senator



Josh Hawley
U.S. Senator

Eric S. Schmitt
U.S. Senator



Roger F. Wicker
U.S. Senator

James Lankford
U.S. Senator