MARCO RUBIO
FLORIDA

United States Senate
WASHINGTON, DC 20510-0908

COMMITTEES:
APPROPRIATIONS
FOREIGN RELATIONS
SELECT COMMITTEE ON INTELLIGENCE
SMALL BUSINESS AND ENTREPRENEURSHIP
SPECIAL COMMITTEE ON AGING

October 30, 2024

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

The Honorable Alejandro Mayorkas
Secretary
U.S. Department of Homeland Security
3801 Nebraska Avenue NW
Washington, D.C. 20016

Dear Commissioner Califf and Secretary Mayorkas:

I write with regard to recent reports identifying two pharmaceutical producers based in the Xinjiang Uyghur Autonomous Region (XUAR) of the People's Republic of China (PRC) that are permitted by the U.S. Food and Drug Administration (FDA) to distribute their products in the U.S. This is in clear violation of current law which prohibits imports from the region due to the Chinese Communist Party's (CCP) egregious human rights abuses, including genocide, forced abortions, and forced sterilizations. Aside from the significant national security and public health risks associated from sourcing and distributing pharmaceuticals and active pharmaceutical ingredients (APIs) from the PRC, banning companies likely engaging in forced human labor and human rights abuses from doing business in the United States is a foundational tenet of promoting freedom and democracy, and is the reason for the enactment of the *Uyghur Forced Labor Prevention Act* in 2021. I urge you to rectify this dangerous transgression of the law and immediately ban all distribution of products from these companies in the United States. I also urge you to conduct a thorough review of all companies currently authorized by the FDA to distribute pharmaceuticals or APIs in the U.S., and assess whether additional companies should be prohibited from distribution under current laws and regulations.

The *Uyghur Forced Labor Prevention Act* ensured that the CCP is held accountable for its use of slave labor and that products made using forced labor would no longer be distributed in any American supply chain. The U.S. has the responsibility of ensuring pharmaceutical and API products are made ethically before distributing to consumers. However, recent analysis by the Centers for Advanced Defense Studies exposed that the FDA currently allows at least two pharmaceutical producers, Xinjiang Nuziline Bio-Pharmaceutical Co. and SEL Biochem Xinjiang Co. to import APIs and drug products into the U.S. Both of these companies are linked to slave labor in Xinjiang and are not listed on the UFLPA Entity List.[1] By including these companies on the FDA's Registered Drug Establishments Site, they are able to legally import into the United States, despite being prohibited under current law.

[1] https://c4ads.org/wp-content/uploads/2024/10/SideEffects-C4ADS.pdf, Page 10

I am concerned that the FDA and the U.S. Department of Homeland Security (DHS) has not conducted sufficient oversight into the pharmaceutical and API producers allowed to conduct business in the U.S., nor made sufficient efforts to uphold U.S. law. The *Uyghur Forced Labor Prevention Act* assures the American people that the products they purchase were made without slave labor. It is clear that the lack of oversight by the FDA has not made this true. The FDA and DHS have a responsibility to rectify this dangerous error and uphold the law. Therefore, I demand both departments and the Forced Labor Enforcement Task Force to immediately place Xinjiang Nuziline Bio-Pharmaceutical Co. and SEL Biochem Xinjiang Co. on the UFLPA Entity List. I also ask that the FDA and DHS complete a thorough review of every company authorized to distribute pharmaceuticals and API in the United States to ensure compliance with the *Uyghur Forced Labor Prevention Act.* I ask that you provide a formal response outlining the FDA and DHS's commitment to complete these actions.

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

Sincerely,

Marco Rubio
U.S. Senator