

February 7, 2024

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

Dear Commissioner Califf:

I write with concern about the widespread importation and distribution of illicit Chinese disposable e-cigarettes in the United States. Foreign disposable e-cigarette manufacturers, the majority of which are based in the People's Republic of China (PRC), are taking advantage of regulatory loopholes and lax enforcement by the Food and Drug Administration (FDA) to flood the market with untested, unapproved devices. As a result, millions of American consumers—including minors—have unwittingly used illegal and potentially dangerous vapes at great risk to their health and safety.

The FDA's approach to regulating the e-cigarette market has enabled this explosion of illicit Chinese vapes. Law-abiding American companies wait years, spend millions of dollars, and comply with strict restrictions on flavors and marketing in order to gain FDA approval for their products. Meanwhile, unscrupulous Chinese companies send shipping containers full of illegal e-cigarettes into our country every day, right under the nose of the FDA and U.S. Customs and Border Protection (CBP). FDA's attempts at enforcement have proven totally inadequate. Chinese companies have circumvented blacklists by misrepresenting their products on shipping manifests and simply by changing their trade names.

The FDA's regulatory double standard has had predictable consequences: legitimate products are few and far between, while dangerous and illegal Chinese vapes dominate the market. Currently, only domestic e-cigarette manufacturing sites are required to register with the FDA and undergo routine inspections, while foreign vaping manufacturers have no requirement for routine oversight. Disposable Chinese vapes with illegal levels of nicotine, and deadly substances like fentanyl, have been found in the United States in growing numbers. With more than 2.1 million youth using e-cigarettes and 4.5 percent of all adults using e-cigarettes, the presence of so many dangerous and untested products is unacceptable and should spur the FDA to significant action.

Some Chinese e-cigarette companies have taken advantage of FDA's lack of enforcement as an excuse for their illegal business, with a spokesman for Heaven Gifts, a Chinese disposable e-cigarette company, describing the regulations as incoherent and unclear. Often, retailers have no way to discern between a product that has undergone FDA approval and one that has not,

unintentionally putting their customers at risk. Foreign vaping companies are tricking retailers about the regulatory status of their products to turn a profit.

It is imperative that the agency take a proactive role in combatting illegal Chinese vapes. I respectfully request that you provide answers to the following questions:

1. How is the FDA ensuring the safety of imported vaping products for consumers?
2. How is the FDA ensuring that all importers of vaping products understand the health and safety standards required to legally sell their products in the United States?
3. Does the FDA intend to publish a rule that would require foreign tobacco product manufacturers to register, and be inspected, by the agency in the immediate future?
4. How is the FDA working with agencies like CBP and the Department of Justice to stop harmful, illicit vaping products from reaching store shelves?
5. What resources are available for e-cigarette consumers and American retailers to educate themselves about the prevalence and dangers of illicit vaping products from their distributors?
6. What, if any, action has the FDA taken to ensure that illicit vaping companies that are caught do not rebrand and import their products again without completing the approval process?
7. How can Congress further support the FDA in cracking down on these malign actors?

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

Sincerely,



Marco Rubio  
U.S. Senator