

February 13, 2023

The Honorable Robert M. Califf, MD  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Building 32, Room 2346  
Silver Spring, MD 20993

Dear Commissioner Califf:

I am writing this letter to you to ask that you review the manner in which the FDA's Center for Tobacco Products engages our small nine-year-old business of 5 employees. We have reached out to CTP numerous times over the years asking for assistance with adhering to regulations, and we have been stonewalled. No clear regulations have been provided to us, and the office for small business compliance hasn't responded to our requests for help.

The only time we hear from the FDA is when something negative is communicated to us. We were surprised last year with an investigator on-site. It feels like CTP's only goal is to scare us out of business. These sorts of reactionary actions committed by CTP towards our small business are more thoroughly described by the Reagan-Udall Foundation report that was commissioned for you in December of last year. I have attached this report as well as our communications with CTP for your review.

The current administration promised to lean on science, not politics, for its regulatory decisions. I am asking you to review our communications with CTP as well as the Reagan-Udall Foundation report when deciding how to guide CTP on its regulatory mission.

John Fitch  
Owner - TBD Liquids