TBD Liquids
997 Piner Rd.
Santa Rosa, CA 95401 USA

2-13-2023
Re: Refusal to File

Grace Kaiyuan, M.B.A., MT(ASCP)
Regulatory Health Project Manager
Office of Science, Center for Tobacco Products
10903 New Hampshire Ave.
Silver Spring, MD 20993 USA

Dear Ms. Kaiyuan,

We appreciate the recent communication we received from the FDA regarding our submission.

We understand that the FDA is refusing to file applications for our products. We previously contacted CTP regarding the unique challenges our small business faced in meeting expectations and difficulties concerning vague language. In response, we were given a brief overview of what the FDA would expect from our applications and no one from the small business team reached out to us to assist with our applications despite our request.

Our application was submitted based on the June 2019 Final Guidance supplied by CTP via e-mail in August of 2020. See attached for this communication as well as the accompanying guidance for which we based our application.

It took two years for the FDA to contact us directly again, and this was with a surprise visit by an FDA investigator. I spent multiple days with Ms. Chalapong, and we were able to fulfill all of the requests that she had. We haven't been notified of any problem areas that Ms. Chalapong was concerned about. While she was here, she seemed pleased with the ways in which we have operated and self-regulated.

It's unsettling that the only time we can reliably get in touch with someone of note at the FDA, it's some sort of warning or negative action that requires me to spend hours writing or gathering documents under fear. I was contacted by three separate people at the FDA last Monday when this "refusal to file" was generated. If I had been provided with the assistance I requested back in 2020, perhaps CTP's frequently shifting and vague requirements for our Environmental Assessment could have been satisfied in 2023.

I'm disheartened that despite the change in commissioner, CTP is still operating in a reactionary manner when it comes to regulating our small business. Instead of reaching out proactively and discussing specific requirements with us, over two years later CTP calls, e-mails, and registered mails that you've decided to refuse to file our application and that all of the products we've been selling for over 8 years are no longer allowed to remain on the market.

Effectively, our small 9-year-old local business with 5 hard-working employees needs to shut down because the Environmental Assessment, which was only ever vaguely described in guidance prior to the initial application deadline, doesn't satisfy the ever-shifting requirements of CTP.

This excerpt of the report prepared last year by the Reagan-Udall Foundation is directly relevant -

> *The Panel recognizes that developing regulations and product standards is time-consuming and resource-intensive, but the long-term benefits are significant. Legally binding parameters described in regulation establish basic principles that can be used in product application reviews and enforcement actions. This structure generates efficiency, eliminating the need for case-by-case adjudications of some issues. Guidance documents can take less time to develop than regulations and can be used to convey FDA's expectations for matters where a binding regulation may not be needed or where the Agency's thinking is evolving and is not yet ripe for inclusion in a binding regulation. Guidance is more readily changed when the science, or needs of FDA, or the regulated community, change.*
>
> *The current CTP process for developing and issuing regulations and guidance is insufficiently informed at the outset about the needs of CTP staff and various stakeholders. CTP could strengthen the quality and usefulness of its policy development function by gathering more input from staff and the public at the front end of the process.*

I have attached the full operational evaluation of CTP prepared for FDA Commissioner Califf last December.

Furthermore, the Environmental Assessment we included with our application was based on a study of a vapor-based tobacco product (IQOS) that the FDA granted a marketing order for six years ago, around the same time that the Final Guidance for our industry was issued. Our products produce significantly lower air pollutant emissions than the IQOS, yet we're given a refusal to file our application years later and Phillip Morris' markedly more harmful product to the environment is given early approval by CTP.

Less than a month ago, the Fifth Circuit Court of Appeals ordered that the cases of two US-based vapor companies that filed petitions for review against the Food and Drug Administration (FDA), be reheard en banc. These two companies were in a similar position as we find ourselves now. I am notifying CTP that we are going to continue to sell our products pending the outcome of the FDA's current cases.

We also want to once again invite the small business compliance team, which we were told exists to help unique companies such as ours meet regulatory requirements, reach out and work with us. We are always happy and willing to meet expectations that are clearly communicated by CTP as was demonstrated last August when Investigator Chalapong spent time with us on-site reviewing our operations.

Sincerely,

John Fitch
Owner - TBD Liquids