TBD Liquids
997 Piner Rd.
Santa Rosa, CA 95404

June 15, 2023

Food and Drug Administration
Center for Tobacco Products
Office of Compliance and Enforcement
10903 New Hampshire Avenue
Silver Spring, MD 20993

Subject: Request for Supervisory Review of Pre-Market Tobacco Product Application

To whom it may concern,

I am writing to request a supervisory review of our pre-market tobacco product application (PMTA) that was refused to be filed by the FDA. The refusal was based on the grounds that our application did not contain an environmental assessment, despite the fact that we provided extensive information on the environmental effects of our products. We kindly ask for your attention to the following facts regarding our application: PM0004179.PD1 – PM0004179.PD4

1. 43% of our PMTA was dedicated to assessing the environmental effects of our products. We believe we have made a comprehensive and diligent effort to evaluate the potential impact of our products on the environment.

2. The findings of our environmental assessment clearly demonstrate that, when compared to traditional cigarettes, our products will have no significant adverse impact on the environment. We have taken into consideration various factors such as waste generation, product disposal, and the use of sustainable materials.

3. As supporting evidence, we have attached the approval from our nicotine supplier, which permits the use of their environmental assessment from their tobacco product master file to bolster our own PMTA. This demonstrates our commitment to providing relevant information and meeting regulatory requirements.

4. Our Environmental Assessment was developed based on the guidance the FDA provided years ago. If there are new or updated requirements that the FDA wishes to see fulfilled in our environmental assessment, we kindly request clear and concise instructions so that we may promptly address those concerns.

5. As a small business operating since 2014, we have diligently sought guidance and clarification on the FDA's requirements through multiple channels. Regrettably, our attempts to communicate with the small business assistance team have been met with auto-response emails. Additionally, our requests for callbacks have not been fulfilled. We have made two prior attempts to contact the FDA seeking clarification on requirements but have been unable to receive a response. Given our size and limited resources, we greatly value the guidance and support from the FDA to ensure compliance.

In light of the above circumstances, we kindly request an in-person review of our application with Dr. Brian King, or another designated representative from the FDA. We believe that a face-to-face discussion will provide an opportunity to clarify any concerns, address any new requirements, and present our case in a more comprehensive manner.

We sincerely appreciate the FDA's commitment to safeguarding public health and the diligence exercised in reviewing tobacco product applications. We are fully committed to meeting all regulatory requirements and providing a transparent assessment of our products.

Thank you for considering our request for a supervisory review of our PMTA. We eagerly await your response and the opportunity to further discuss our application.

Sincerely,

John Fitch

Owner