



Howard A. Willard III
Chairman and Chief Executive Officer

February 8, 2019

Dr. Scott Gottlieb
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Commissioner Gottlieb:

We are in receipt of your letter of February 6, 2019 expressing concern about our investment in JUUL Labs, Inc. As you know, on the eve of our transaction with JUUL Labs in December, we contacted your office to inform you of the investment and to request a meeting to explain the reasons for the investment. We were told to submit a formal request for a meeting, which we did on January 6, 2019. On February 6, we received your letter requesting a meeting, as if we did not have a formal meeting request already pending on the same subject. We are disappointed by this and by the release of the February 6 letter without proper context.

Although a month has passed, we continue to hope you will schedule a meeting with us and JUUL so we can directly discuss these important issues. In the meantime, let me take this opportunity to briefly describe our ongoing commitment to addressing underage use of e-vapor products and our pursuit of tobacco harm reduction for adult smokers.

On December 20, 2018, we announced a minority investment in JUUL Labs, Inc. As part of that transaction, we entered into service agreements with JUUL Labs designed to accelerate JUUL's mission to switch adult smokers to e-vapor products. In entering this relationship with JUUL, we believed we were taking significant action to promote smoker conversion to non-combustible tobacco products – entirely in line with FDA's policies, as you announced in July 2017. In fact, we are aware of no other action taken by anyone that promises to do more to accelerate the conversion of smokers to non-combustible products.

The services agreement also opens the door to allowing us to help JUUL with its youth prevention efforts and social responsibility efforts, tapping into our decades of expertise in addressing these important issues. We know that addressing the rise in youth usage of e-vapor products is essential to accomplishing the mission to convert adult smokers to less risky alternatives. These two goals must be accomplished together.

In terms of our own actions, as you know, we have taken such steps as:

- Announcing our support and increased advocacy for federal legislation to establish 21 as the minimum age to purchase tobacco products. Since our meeting with you in October, we have also increased support and advocacy for state legislation to establish 21 as the minimum age to purchase tobacco products. In fact, we have submitted statements or testified in several states encouraging an increase of the minimum age to 21.
- Reaffirming our ongoing and long-standing investment in underage tobacco prevention efforts, including retailer related communications and training on the importance of preventing underage access to all tobacco products.

We believe our investment in JUUL Labs, Inc., is consistent with our prior statements and actions. Although we have no authority to speak on JUUL's behalf, they already have taken significant actions to address the concerns related to youth use of e-vapor products, including announcing:

- Restrictions on the sale of flavored pods and temporarily stopping their distribution to traditional retail outlets; this includes undertaking efforts to retrieve certain flavor pods from retail.
- Limiting the expanded distribution through Altria's sales organization to no more than an additional 20,000 stores in 2019.
- Active pursuit of raising the minimum age to 21 for purchase of all tobacco products
- Enhancements to their online platform to further ensure consumers are 21 or older and to limit bulk purchases of their products to help address FDA's concern over "straw purchases;"
- *A Restricted Distribution System* at retail for certain flavored products;
- Exiting from U.S. social media platforms;
- Developing user authenticated technologies that can restrict use; and
- Retail and online monitoring and enforcement programs.

These unilateral actions by Altria and JUUL collectively address the significant problem of youth use of e-vapor products. However, we think more can be done. For example, not all other manufacturers have taken similar actions, and in some cases, copy-cat products have begun to appear, with names and flavors (such as "Cotton Candy") that pose problematic enticements to youth. This is an area for continued focus.

I hope we can meet soon to directly discuss these issues.

Sincerely,

A handwritten signature in blue ink, appearing to read "Howard A. Willard III".

Howard A. Willard III