



Altria

Howard A. Willard III
Chairman and Chief Executive Officer

October 25, 2018

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

Dear Commissioner Gottlieb:

On behalf of Altria Group, Inc. and our subsidiary Nu Mark LLC (“Nu Mark”), I write in response to your September 12, 2018 letter raising serious concerns about underage access to and use of e-vapor products. We share your concerns and believe kids should not use any tobacco products.

Importantly, we are alarmed about the reported rise in youth e-vapor use to epidemic levels, and we are concerned that these youth issues may jeopardize harm reduction for adult smokers. In your July 2017 announcement, you highlighted the importance of the continuum of risk and embraced a policy of encouraging smokers to migrate to non-combustible forms of tobacco products. We believe e-vapor products present an important opportunity for adult smokers to switch from combustible cigarettes. Yet, the current situation with youth use of e-vapor products, left unchecked, has the potential to undermine that opportunity for adult smokers. Because we believe in the long-term promise of e-vapor products and harm reduction, we are taking immediate action to address this complex situation.

Specifically, as explained further below, we announced today the following actions:

- We will remove from the market our *MarkTen Elite* and *Apex by MarkTen* pod-based products until we receive a market order from FDA or the youth issue is otherwise addressed;
- For our remaining *MarkTen* and *Green Smoke* cig-a-like products, we will sell only tobacco, menthol and mint varieties. We will discontinue the sale of all other flavor variants of our cig-a-like products until we receive a market order from FDA or the youth issue is otherwise addressed; and
- We will support federal legislation to establish 21 as the minimum age to purchase any tobacco product.

Of course, we recognize the impacts these decisions will have on our consumers, trade partners, suppliers and others. Nonetheless, these actions are essential to addressing the youth epidemic and preserving the long-term harm reduction opportunity of e-vapor products.

By way of background for our actions, Nu Mark's e-vapor portfolio consists of two primary product types – our *MarkTen* and *Green Smoke* cig-a-like products and *MarkTen Elite* and *Apex by MarkTen* pod-based products. Our e-vapor products are available to adult consumers in a variety of flavors at retail and through our e-commerce sites. Our marketing efforts for these products have been focused on communicating directly with adult tobacco consumers while minimizing the reach of our communications to unintended audiences. We have long supported efforts at retail to prevent youth access through identification checks, retailer training and other age verification practices. Similarly, we employ strong age-verification technologies and practices on our e-commerce sites to sell only to adult consumers age 21 and older.

Based on the publicly available information from FDA and others, we believe that pod-based products significantly contribute to the rise in youth use of e-vapor products. Although we do not believe we have a current issue with youth access to or use of our pod-based products, we do not want to risk contributing to the issue. To avoid such a risk, **we will remove from the market our *MarkTen Elite* and *Apex by MarkTen* pod-based products until we receive a market order from FDA or the youth issue is otherwise addressed.**

We believe underage use of e-vapor products is further compounded by flavors in these products that go beyond traditional tobacco flavors. This presents a challenge from a tobacco harm reduction perspective. We believe, informed by data collected in preparing our Pre-Market Tobacco Applications (“PMTAs”), that flavors play a critical role in migrating adult smokers to non-combustible forms of tobacco products. In fact, we have shared some of this evidence at recent scientific conferences, including: (1) that seven or more flavor varieties for *MarkTen* played an important role in reducing the number of cigarettes per day or switching completely among adult tobacco users; and (2) adult tobacco non-users did not find *MarkTen* flavors appealing.¹

Even though we believe flavors play an important role from a tobacco harm reduction perspective, we recognize the need to take action. **For our remaining *MarkTen* and *Green Smoke* cig-a-like products, we will sell only tobacco, menthol and mint varieties. We will discontinue the sale of all other flavor variants of our cig-a-like products until we receive a market order from FDA or the youth issue is otherwise addressed.** While we do not believe we currently have a youth issue associated with our

¹ Presentation by Altria Client Services at the 72nd Tobacco Science Research Conference, September 18, 2018:
<http://www.altria.com/ALCS-Science/ConferenceDocumentLibrary/2018%20TSRC%20J%20Zdniak%20Presentation.pdf>