Howard A. Willard III
Chairman and Chief Executive Officer

Altria

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.

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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

cig-a-like products or their flavors, we again do not want to risk contributing to the issue. This also still allows current adult tobacco consumers looking for smoking alternatives to continue to have access to traditional tobacco, menthol and mint flavors in cig-a-like e-vapor products.

Recognition of the importance of the PMTA product review pathway is inherent in our actions. The PMTA pathway creates the opportunity for a manufacturer to provide data and evidence to support its request for marketing authorization and to demonstrate that the products are "appropriate for the protection of public health." FDA's review of PMTA submissions, as well as requiring post-market surveillance, also allows the Agency to make informed science- and evidence-based decisions about products. To make this pathway as clear and viable as possible, we encourage the FDA to fully engage in notice-and-comment rulemaking to establish appropriate scientific and other standards for the efficient review of PMTA applications. This could include an expedited PMTA pathway for non-combustible products with enhanced post-market surveillance to ensure the products are not appealing to unintended audiences. Moreover, we recommend that FDA commission and publish data as to youth usage on a more frequent basis so that there is timely surveillance.

Altria and its tobacco operating companies have a long history of investing in and supporting underage tobacco prevention efforts. We believe that the current youth issue is driven, in part, by social access – that is, the purchase of such products by consumers of legal age for use by minors. **We believe, in the face of these current e-vapor and youth-related concerns, now is the time to support federal legislation to increase the minimum legal age to purchase tobacco products to age 21 and to set a national standard**. We recognize that FDA does not have the authority to increase the minimum legal age. We will share our views with members of Congress and encourage them to consider an increase in the minimum age to 21 to purchase tobacco products as part of their tobacco-related legislative priorities. Other enhancements we support include requiring user fees for e-vapor products, banning vaping in schools and prohibiting self-service displays at retail.

In your letter to us, you raised additional potential actions for us to consider related to marketing practices, online sales practices and retailer compliance practices. Let me address our current practices in each of these areas.

We focus our marketing practices for our e-vapor products on communicating with adult tobacco consumers while limiting reach of our communications to unintended audiences.

Nu Mark's branded direct mail and email communications are sent only to age-verified adult smokers and vapers age 21 or older, and in-person communications are limited to age-verified smokers and vapers as well. Digital advertisements are only placed on third-party websites with predominantly adult visitors, and we do not currently maintain a branded presence on social media sites. Print advertisements are placed in adult

publications with predominantly adult readership. We do not use advertising images of anyone who is, or appears to be, under 25 years of age.

We do not use television, radio, billboard or transit advertising. We do not use celebrities in connection with the marketing of our products, and we do not allow sponsorship of events with brand names such as *MarkTen*. We do not distribute branded merchandise, other than accessories like USB battery chargers that are branded to indicate the intended use of the accessory. Nu Mark declines all third-party requests for payment, product samples or permission to use or display our e-vapor brands in any movies, television shows, video games or other public entertainment media. Nu Mark also complies with all FDA requirements and restrictions for the marketing and sale of its products, including the prohibition on sampling, required warnings on labeling and advertising, and minimum age to purchase.

With respect to e-commerce transactions on our websites, we have controls in place to help ensure our products are sold only to adults who are 21 or older. We require consumers to affirm that they are age 21 or older and a current adult smoker or vaper prior to accessing our sites, and our content displayed to consumers entering the site contains product-focused imagery with limited use of lifestyle imagery. We require age verification to purchase e-vapor products and accessories and to receive promotional emails, direct mail or coupons from our brands. Our age verification practices rely on robust technology tools and public database information to verify age. In states that do not allow the use of third-party electronic age verification, consumers must submit government-issued identification to establish that they are 21 years of age or older.

We have long supported actions at retail to limit youth access to tobacco products, including e-vapor. Most of the retailers who sell Nu Mark's e-vapor products get those products from distributors. To limit youth access to its products at retail, Nu Mark's promotional contracts require retailers to sell its products in a non-self-service manner, commit not to selling to youth and comply with the law. We currently monitor the FDA's compliance checks and monitor any No Tobacco Sales Orders ("NTSO") to determine whether any of our contracted accounts are subject to an NTSO. We continue our financial support of the *We Card* program providing training and age-verification tools to retailers. And, our retail signage is product-focused and intended to convey product availability, price and product attributes at the place of purchase.

In addition to our existing practices outlined above, we will continue to evaluate other actions we can take to strengthen our overall approach to how we market and sell our e-vapor products with the goal of limiting the reach of our communications to unintended audiences.

We support adult tobacco consumer choice and the promise of tobacco harm reduction, and we fully intend to offer a compelling portfolio of e-vapor products for adult smokers and vapers through FDA's product review pathways or when underage use of e-vapor is otherwise addressed. Yet, it is clear that underage access to and use of certain e-vapor products is a serious threat to the long-term promise of harm reduction. We are committed to helping reverse the current use trend among youth in order to preserve that long-term opportunity.

Please let me know if you have any questions related to our actions.

Thank you.

Sincerely,

Howard A. Willard III

cc: Ms. Imelda Paredes, J.D.
Senior Regulatory Counsel
Center for Tobacco Products

Mr. Mitchell Zeller, J.D.
Director
Center for Tobacco Products