Altria

Altria Client Services

James E. Dillard III
Senior Vice President
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October 10, 2013

The Honorable Margaret A. Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Commissioner Hamburg:

On behalf of Altria Group's tobacco operating companies,[1] I write to express our support for thoughtful U.S. Food and Drug Administration ("FDA" or "Agency") regulation of all currently unregulated tobacco products as defined under the Family Smoking Prevention and Tobacco Control Act ("FSPTCA").[2]

Altria Group is the parent of leading tobacco companies in the United States. Our currently regulated operating companies Philip Morris USA Inc. and U.S. Smokeless Tobacco LLC compete in the cigarette and smokeless tobacco categories. John Middleton Company competes in the large machine-made cigar and pipe tobacco categories. Altria is also the parent of Nu Mark LLC, which develops and markets innovative tobacco products for adult tobacco consumers, including MarkTen™ electronic cigarettes and VERVE® discs, which both contain tobacco-derived nicotine.

Altria Group, on behalf of its tobacco operating companies, actively supported the passage of the FSPTCA for more than eight years because we believe a comprehensive regulatory framework, thoughtfully implemented, can contribute to resolving many of the complex issues that surround tobacco products. We continue to believe that reasonable regulation can benefit adult tobacco product consumers by providing a framework to evaluate tobacco products that are potentially

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[1] Philip Morris USA Inc. ("PM USA"), U.S. Smokeless Tobacco Company LLC ("USSTC"), John Middleton Co. ("Middleton") and Nu Mark LLC ("Nu Mark") are wholly-owned subsidiaries (either directly or indirectly) of Altria Group, Inc. ("Altria"). Altria Client Services Inc. ("ALCS") provides certain services, including regulatory affairs, to the Altria group of companies. "We" and "our" are used throughout to refer to PM USA, USSTC, Middleton and Nu Mark.

[2] *See generally*, Federal Food, Drug, and Cosmetic Act § 901.

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less harmful than conventional cigarettes and by creating clear principles for accurate and scientifically grounded communications to them.

We support FDA extending appropriate regulatory authority over all tobacco products, including those containing tobacco-derived nicotine such as e-cigarettes (and those types not yet marketed), for these same compelling reasons. We agree with FDA's previous statements that certain "general controls" are appropriate for regulating newly deemed tobacco products.[3] These areas include:

- Registration
- Product listing
- Ingredient listing
- Good manufacturing practice requirements
- User fees
- Adulteration and misbranding provisions
- Premarket review requirements

We also believe all tobacco products containing tobacco-derived nicotine should be age restricted, and therefore support legislation in the states and FDA regulation mandating a minimum age to purchase tobacco products that are not currently subject to age restriction. We also support legislative efforts and FDA regulation to restrict underage access to tobacco products such as provisions that require all tobacco products be sold in a non-self-service manner. At the same time, any regulation should reflect Congress's intent for FDA to respect adult tobacco consumer choice.

By extending its authority to all tobacco products, FDA will bring all tobacco products, for the first time, under a single public health regulatory authority. This presents the Agency with an unprecedented opportunity to advance public health goals by recognizing that some types of tobacco products may have significantly lower risks compared to cigarettes. Importantly, we believe FDA should adopt a regulatory framework, grounded in science and evidence, that recognizes the differences in tobacco products and fosters innovation in tobacco products that may have the potential to benefit public health.

At the same time, FDA should reject the call by some to stifle innovation and adopt a "one-size-fits-all" approach to regulating tobacco products. Such an approach does not reflect the harm reduction potential of lower risk products and could have the real-world consequence of preventing new forms of tobacco products from playing an important role in harm reduction.

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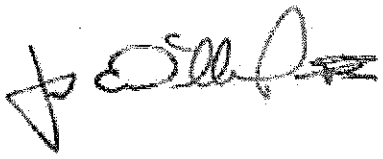
[3] See *FDA Letter to Stakeholders: Regulation of e-cigarettes and Other Tobacco Products*, April 25, 2011

We believe effective regulation benefits from industry perspective and insight. We have actively shared our perspectives and expertise on important regulatory matters with FDA. We will continue to do so as the Agency proposes and implements regulation of all tobacco products.

Thank you for your attention.

Sincerely,



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cc: Mitchell Zeller, J.D.