Altria
Altria Client Services

James E. Dillard III
Senior Vice President
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May 5, 2014

Mr. Mitchell Zeller
Director, Center for Tobacco Products
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: 79 Fed. Reg. 23,142 (April 25, 2014) Proposed Rule – Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Request for Extension of Public Comment Period

Dear Mr. Zeller:

Altria Client Services ("ALCS"), on behalf of Philip Morris USA Inc. ("PM USA"), John Middleton Company ("Middleton"), Nu Mark LLC ("Nu Mark") and U.S. Smokeless Tobacco Company ("USSTC"),[1] writes in response to the April 25, 2014, Proposed Rule on deeming of tobacco products. The Proposed Rule states that FDA will accept comments, data, research and other information in response to the Proposed Rule until July 9, 2014.[2] We respectfully request that FDA extend the 75- day comment period an additional 75 days. We base our request on the following considerations.

In addition to requesting comments on the Proposed Rule itself, FDA requests comments on more than a dozen specific topics including how to regulate potentially less hazardous products, warnings, different options to regulate cigars, and "different regulatory mechanisms" for newer tobacco products, among others.[3] The Proposed Rule and the other topics raised by FDA are important, numerous and warrant thoughtful consideration by regulated manufacturers and others.

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[1] PM USA, Middleton, Nu Mark and USSTC are wholly-owned subsidiaries of Altria Group, Inc. ("Altria"). ALCS provides certain services, including regulatory affairs, to the Altria family of companies. "We" and "our" are used throughout to refer to PM USA, Middleton, Nu Mark and USSTC.

[2] *See* 79 Fed. Reg.23,142 (April 25, 2014);
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm394667.htm

[3] *See* 79 Fed. Reg. at 23,144-5.

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The Agency has been evaluating its approach to the deeming of tobacco products for several years. FDA is now providing the public, including regulated manufacturers, only 75 days to provide substantive comments on both the Proposed Rule and the other topics on which the Agency seeks comments, data, research and other information. By contrast, the Agency eventually provided 120 days to respond to its Advanced Notice of Proposed Rulemaking on the use of menthol in cigarettes[4]. It also opened with a 181-day docket to solicit public comment on the issues related to third-party governance of industry-funded research.[5]

We support the Agency's commitment to solicit information related to the potential deeming of tobacco products and intend to provide the Agency our perspectives. Accordingly, we ask the Agency to provide the public an additional 75 days to provide thoughtful, science- and evidence-based responses and information to inform FDA's future decision-making. We hope the Agency can respond to the request, as well as any others it receives, quickly so that we can plan accordingly. We appreciate your consideration of our request.

Sincerely,

James E. Dillard III

[4]78 Fed. Reg. 55,671 (Sept. 11, 2013).
[5]78 Fed. Reg. 19,713 (April 4, 2013).