



**Jose Luis Murillo**  
Vice President  
Regulatory Affairs

April 6, 2018

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, Maryland 20852

**Re: Docket No. FDA-2017-N-6107 (83 Fed. Reg. 12,901, March 26, 2018) Advance Notice of Proposed Rulemaking on Regulation of Premium Cigars – Request for Extension of Public Comment Period**

Altria Client Services LLC (“ALCS”), on behalf of Philip Morris USA Inc. (“PM USA”), John Middleton Company (“JMC”), and Sherman Group Holdings LLC and its subsidiaries (“Nat Sherman”)<sup>1</sup> writes in response to the March 26, 2018, Advance Notice of Proposed Rulemaking (“ANPRM”) regarding the regulation of premium cigars. The ANPRM asks two dozen enumerated questions, which are broad in scope, and states that FDA is seeking comments, data, research, and other information responsive to these questions through June 25, 2018.<sup>2</sup> Given the number, scope, magnitude, and subject matter of these questions, we respectfully request that FDA extend the 90-day comment period an additional 90 days. We base our request on the following considerations.

The Agency poses thorough questions that solicit detailed responses. Question two alone, regarding the “defining characteristics” of premium cigars, seeks evaluation of a minimum of 18 individual “characteristics.” FDA’s questions also include requests for information from studies covering 20 separate topics ranging from premium cigar labeling to nicotine concentration in premium cigars.

Adding to the complexity, the issues raised by this ANPRM are intertwined with other regulatory actions that FDA is considering as part of its “comprehensive public health package.” Another ANPRM, published on March 16, 2018, seeks comments on developing a product standard to set

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<sup>1</sup> PM USA, JMC, and Nat Sherman are wholly-owned subsidiaries of Altria Group, Inc. (“Altria”). PM USA manufactures cigarettes, JMC manufactures cigars and pipe tobacco, and Nat Sherman manufactures cigarettes, cigars and pipe tobacco. ALCS provides certain services, including regulatory affairs, to the Altria family of companies. “We” and “our” are used throughout to refer to PM USA, JMC, and Nat Sherman.

<sup>2</sup> See 83 Fed. Reg. 12,901 (March 26, 2018), available at: <https://www.federalregister.gov/documents/2018/03/21/2018-05655/regulation-of-flavors-in-tobacco-products>.

Altria Client Services LLC  
2325 Bells Road  
Richmond, Virginia 23234  
(804) 335-2879  
Joe.Murillo@altria.com

a maximum nicotine level for cigarettes. A second ANPRM, published on March 21, 2018, seeks comments on the regulation of flavors in tobacco products. Responses to these ANPRMs are also due in 90 days, and ALCS will be working on its responses to these ANPRMs concurrently and utilizing many of the same subject matter experts for all three.

For the reasons stated above, we request FDA provide an additional 90 days for public comments. We urge FDA to grant this request within two weeks. A prompt response will facilitate effective planning by all interested parties and reduce unnecessary and unproductive disruptions that will occur if FDA were to wait until late in the response period before granting this request.

We appreciate your consideration of our request.

Sincerely,

A handwritten signature in blue ink, appearing to read "Jane L. ...". The signature is written in a cursive style and is positioned below the word "Sincerely,".