



April 16, 2018

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

RE: Docket No. FDA-2017—N-6565 (83 Fed. Reg. 12,294, March 21, 2018) Advanced Notice of Proposed Rulemaking on Regulation of Flavors in Tobacco Products – Request for Extension of Public Comment Period

Dear FDA Representative:

The National Association of Tobacco Outlets, Inc. (NATO) submits this letter to respectfully request additional time to respond to the March 21, 2018, Advanced Notice of Proposed Rule Making (ANPRM) regarding the regulation of flavors in tobacco products. NATO is a national trade association that represents more than 60,000 retail stores across America and we would appreciate an opportunity to survey our members, collect responses, and articulate those responses in a timely fashion for submittal to the agency. However, to achieve this outcome, NATO respectfully requests that the FDA consider extending the current 90-day comment period by another 90 days.

In the ANPRM, the FDA states that the agency is seeking research, data and information regarding the possible regulation of flavors in tobacco products. An extension of the public comment period by an additional 90 days, would provide a better opportunity for NATO, its retail members, and other interested stakeholders to compile the requested research, data, and information to respond to the 25 separate questions across 6 different categories that are outlined within this ANPRM which encompass significant complexity and scope. The current deadline of June 19, 2018 for the submission of responses on research, data and other information is not adequate to survey NATO members and compile thoughtful and comprehensive comments.

This issue is compounded by the fact that two other ANPRMs were published by the FDA within a three-week timeframe in March, 2018. The additional ANPRMs published on March 16, 2018 and March 26, 2018 are also complex and significant in scope. Those ANPRMs solicit information regarding a possible product standard for a maximum level of nicotine in cigarettes and comments on the regulation of premium cigars. Taken together, the amount of information requested in each ANPRM which must be addressed concurrently cannot be completed in the proscribed timeframe.

As indicated above, NATO will be surveying its retail membership on the questions outlined in this ANPRM so that the association can provide to the agency thoughtful and clearly articulated information to help guide the FDA in making decisions on this important issue that will have a significant impact moving forward.

For these reasons NATO would appreciate your consideration of our request to extend the public comment period for this ANPRM an additional 90 days past the June 19, 2018 deadline so that the association has adequate time to survey its members and compile the necessary information to respond to this request for research, data, and information with substantive comments regarding the possible regulation of the flavors in tobacco products.

Thank for your consideration and I look forward to hearing from you on this matter.

Sincerely,

Thomas Briant

NATO Executive Director and Legal Counsel