December 8, 2017

The Honorable Rodney Frelinghuysen
Chairman
House Committee on Appropriations
H-305, The Capitol
Washington, DC 20515

The Honorable Nita M. Lowey
Ranking Minority Member
House Committee on Appropriations
H-305, The Capitol
Washington, DC 20515

The Honorable Robert Aderholt
Chairman, House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies

The Honorable Sanford Bishop,
Ranking Minority Member, House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies

Dear House Appropriations Chairmen and Ranking Members:

The American E-Liquid Manufacturing Standards Association (AEMSA) was created in 2012 as the first and only e-vapor trade association completely dedicated to creating and verifying responsible, sustainable standards for quality manufacturing of "e-liquids" used in e-vapor products (sometimes known as electronic cigarettes) to protect consumers. AEMSA recently expanded our organization's membership categories to include all segments of the electronic vapor industry. In addition to e-liquid manufacturing businesses, AEMSA also now includes among our members the industry's leading businesses in e-liquid component manufacturers, vaping hardware manufacturers, and electronic vapor products distributors and retailers.

As president of this industry-leading trade association, I am writing to request that Section 753 of the House Appropriations Committee-passed bill funding the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies for FY 2018 be removed in its entirety in subsequent House action or in a House-Senate Conference on this legislation.

Section 753 deals with: the application of the Tobacco Control Act's grandfather date for electronic vapor products deemed by regulation to be tobacco products; the promulgation of tobacco product standards for electronic vapor products for "characterizing flavors and batteries"; restrictions on advertising, face-to-face sales, labeling of vapor products; and for other miscellaneous matters relating to the regulation of electronic vapor products.

On July 28, 2017, FDA Commissioner Scott Gottlieb announced that "extension of premarket review compliance deadlines covered by this guidance applies to all categories of newly regulated products that were on the market on August 8, 2016, including ENDS (e.g. e-cigarettes and e-cigars), hookah, pipe

tobacco, and cigar. The compliance dates are being extended from November 8, 2018 (PMTAs) to… August 8, 2022 for PMTAs for newly regulated noncombustible tobacco products, such as most ENDS or e-cigarettes)."

As a result of the Commissioner's July announcement which came after your Committee's action on the FDA funding legislation, the dire need for near-term relief to prevent existing electronic vapor products from being subjected to a 2018 PMTA application deadline no longer exists. Accordingly, AEMSA and other like-minded e-vapor industry members believe continued discussions with FDA and the Congress on a comprehensive tobacco harm reduction framework and appropriate new regulation of vapor products separate and distinct from the Tobacco Control Act are preferable at this time to the band-aid approach contained in Section 753.

In fact, given the new Commissioner's views on tobacco harm reduction and the role electronic vapor products can play in reducing tobacco-related harm, retaining Section 753 in your legislation would actually hamper our industry's efforts to provide smokers with a far less harmful alternative by stifling continued innovation in the industry and by continuing to lump deadly, combustible cigarettes in the same regulatory category with electronic nicotine vapor alternatives. With respect to e-vapor products, the Deeming Rule was, unfortunately, outdated the moment it became effective on August 8, 2016 because it immediately prohibited product innovation. Unlike traditional combusted tobacco products, advancements and innovations in e-vapor science and technology have significantly *improved* the safety of the products over the years. However, today even simple changes to, for example, remove potentially harmful flavor compounds from e-liquids, or modify devices and batteries to prevent overheating, would not be permitted without first going through the prohibitively expensive and time consuming, if not virtually impossible, Premarket Tobacco Product Application (PMTA) process. Section 753 would leave this requirement in place into the future and stifle any potential innovation in consumer safety.

While our members in the vaping industry no longer support inclusion of Section 753 in your FY 2018 appropriations legislation, please be assured that we have commended the House support over the past two years for trying to provide near-term, partial relief for our products when we were facing the 2018 PMTA deadline. Also, please be assured that we will continue to work with you and your colleagues in both Houses and on both sides of the aisle to promote tobacco harm reduction to significantly reduce the 480,000 premature deaths each year and the $300 billion in associated health care costs and lost productivity resulting from smoking deadly, combustible cigarettes through continued innovation in electronic nicotine vapor alternatives and tobacco harm reduction.

Sincerely,

Scott Eley
President

Cc: The Honorable Paul Ryan, Speaker of the House of Representatives
The Honorable Nancy Pelosi, House Minority Leader
The Honorable Tom Cole