AEMSA AMERICAN E-LIQUID MANUFACTURING STANDARDS ASSOCIATION

August 28, 2020

Via Electronic Submission

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Division of Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
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RE: Petition for Extension of Premarket Tobacco Product Application Filing Deadline from Keller and Heckman LLP

The American E-liquid Manufacturing Standards Association (AEMSA) appreciates this opportunity to comment on Docket No. Docket: FDA-2020-P-1797

Established in 2012, AEMSA is an all-volunteer 501(c)(6) non-profit organization of American small-business open-system e-liquid manufacturers dedicated to promoting safety and responsibility through self-regulation. AEMSA remains the only vapor industry trade association focused on creating, implementing, and upholding standards for the responsible manufacture and distribution of e-liquids for adult tobacco users. AEMSA has developed facility, ingredient, traceability, delivery, youth-access prevention, and packaging standards that are publicly available for all e-liquid manufacturers, and which have previously been presented to FDA.

AEMSA members are small-businesses committed to complying with, and maintaining compliance to FDA regulations, including premarket review for all new tobacco products. Unfortunately, the COVID-19 pandemic that grips this nation is inhibiting our small-business members from completing robust PMTA submissions, for FDA review, to demonstrate that open-system e-liquid products are appropriate for the protection of public health.

AEMSA has presented to FDA, on numerous occasions, plans that would alleviate the burdens that small-business open-system e-liquid manufacturers face, as well as reduce the burden on FDA in the review of PMTA submissions; all with the goal of protecting public health. Now, given the urgency of both the upcoming PMTA deadline, while dealing with a once

in one-hundred year pandemic, FDA should, for the benefit and protection of public health, extend the PMTA deadline by at least 180 days.

Given the hardships caused as a result of the COVID-19 pandemic, such as those outlined in the citizen's petition, AEMSA member manufacturers will require additional time to complete certain portions of the Premarket Tobacco Application submissions. By way of example, many laboratories and contract research organizations within the United States and abroad, including those with which many AEMSA manufacturers contract to conduct important laboratory and clinical studies, are shutting down or suspending in person work, or reducing it significantly – some as the result of their states' or localities' closures of 'non-essential businesses,' others as a result of company policies implemented to ensure their employees' health and safety. By its nature, this type of laboratory work must be performed in person, on site.

In a declaration made to the district court of Maryland, the FDA stated:

> *"Moreover, as a result of the outbreak, some employees from the FDA's Center for Tobacco Products (CTP) have been deployed to work for the U.S. Public Health Service, including many within one of the divisions of CTP's Office of Science, which is responsible for reviewing premarket applications. Also, virtually the entire FDA staff responsible for reviewing premarket applications will be teleworking until further notice. While the FDA has taken steps to enable work to be performed remotely as much as possible, the agency anticipates that it will take additional time for a remote workforce to receive and process applications and conduct scientific review of those applications."*[1]

Furthermore, the FDA can exempt new tobacco products from this filing requirements for good cause on a case-by-case basis.[2] The hardships caused by COVID-19 justify "good cause" on the basis of the necessity for social-distancing, work-from-home, and adhering to CDC guidelines to prevent the spread of the virus.

How can a better case be made for good cause than what is self-evident at this time?

This exemption has been provided to "premium cigars" and "pipe tobacco", both of which are combustible tobacco products.[3] Indeed, FDA recognized the Court's summary judgment opinion likewise recognizes that "as a matter of its 'enforcement discretion,' the FDA

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[1] Second Declaration of Mitchell Zeller. American Academy of Pediatrics, et. al., v. United States Food and Drug Administration, No. 8:18-cv-00883-PWG

[2] See American Academy of Pediatrics, et al. v. FDA, Case No. 8:18-cv-00883 (2019). As the Court made clear in its Memorandum Opinion, "New products for which applications have not been filed within this period shall be subject to FDA enforcement actions in the FDA's discretion." Id. (emphasis added). The Court further stated that "FDA shall have the ability to exempt [n]ew [p]roducts from [the] filing requirements for good cause on a case-by-case basis." Id. (emphasis added).

[3] American Academy of Pediatrics, et. al., v. United States Food and Drug Administration, Document 188, Filed 8/05/20, 8:18-cv-00883-PWG

may decide not to enforce the provisions of the Tobacco Control Act with regard to specific products."

The Agency's top priority for regulatory oversight should be those products which may appeal more to vulnerable populations, such as youth. FDA makes this case clearly in a request to exempt some combustible tobacco products from the September 9, 2020 deadline: *"The FDA's top priority for premarket review of deemed products remains products that pose the greatest risk for initiation or use by underage persons, such as flavored, cartridge-based e-cigarette products targeted to or easily accessible to youth."*[4]

As previously stated, AEMSA members are open-system electronic nicotine delivery system (ENDS) e-liquid manufacturers. AEMSA does not have, in its membership, manufacturers that specialize in "cartridges-based e-cigarette products targeted to, or easily-accessible to youth." Additionally, AEMSA requires its members to utilize active, third-party age verification providers that are able to adequately verify with some level of certainty that the purchaser of the ENDS products are not below the minimum age to purchase these products.

Other agencies have taken coronavirus-related actions with similar timeframes. FDA should act no differently.

According to the mission statement of the Food and Drug Administration: *"FDA is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health."*[5]

FDA can not accomplish this mission if both FDA and the manufacturers responsible for innovations in alternatives to combustible tobacco are sidelined by the current ongoing threat posed to public health by COVID-19.

We ask that the FDA responds to this citizen's petition swiftly by extending the compliance policy for small, open-systems ENDS e-liquid manufacturer businesses like those represented in our membership.

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[4] American Academy of Pediatrics, et. al., v. United States Food and Drug Administration, Document 188, Filed 8/05/20, 8:18-cv-00883-PWG

[5] https://www.fda.gov/about-fda/what-we-do#:~:text=FDA%20Mission,-The%20Food%20and&text=FDA%20is%20responsible%20for%20advancing,maintain%20and%20improve%20their%20health.

AEMSA appreciates your consideration in allowing additional time to submit Premarket Tobacco Applications, and we believe that keeping small-business open-system e-liquid manufacturers' products on the market under an extended compliance policy is consistent with the Administration's goal of economic recovery and the FDA's mission of protecting public health, provided that manufacturers are taking reasonable steps to prevent youth-access to these new products.

On behalf of AEMSA and its members,

Sincerely,

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AEMSA

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