Scott Eley
President
seley@aemsa.org

December 7, 2017

Via Electronic Submission (http://www.regulations.gov)

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

Re: Request for Comments in Conjunction with the Food and Drug Administration's Implementation of Executive Orders 13771 ("Reducing Regulation and Controlling Regulatory Costs") and 13777 ("Enforcing the Regulatory Reform Agenda"); FDA Docket No.: FDA-2017-N-5095

The American E-Liquid Manufacturing Standards Association (AEMSA) appreciates this opportunity to respond to the Food and Drug Administration's (FDA's or Agency's) request for comments in conjunction with its implementation of Executive Orders 13771 ("Reducing Regulation and Controlling Regulatory Costs") and 13777 ("Enforcing the Regulatory Reform Agenda"), as announced in Docket No.: FDA-2017-N-5095. This comment highlights deficiencies with FDA's "Deeming Rule," 81 Fed. Reg. 28973 (May 10, 2016), which "deems" previously unregulated tobacco products subject to the requirements of the Food, Drug and Cosmetic Act (FDCA), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), and requests the Agency either repeal, replace or significantly modify the rule, which places significant burdens on thousands of small businesses, and will ultimately result in a ban of the vapor industry. As described herein, the law gives FDA significant discretion under its deeming authority to enforce the requirements of the Tobacco Control Act in a manner to achieve meaningful burden reduction for the vapor industry while allowing the Agency to accomplish its public health mission and fulfill its statutory obligations.

I. Background on AEMSA

AEMSA is the first and only manufacturers' trade association completely dedicated to creating responsible and sustainable standards for the manufacturing of E-liquids used in vapor devices, also known as Electronic Nicotine Delivery Systems (ENDS), E-liquid Components, ENDS Hardware Devices, and Distribution/Retail. AEMSA is an all-volunteer 501(c)(6) organization, formed by U.S. manufacturers of e-liquids, to promote safety and responsibility through self-regulation. Our Members believe we have a responsibility to self-regulate e-vapor manufacturing processes and end consumer sales using professional criteria. One of AEMSA's primary goals is to provide consumers and government regulators with confidence that our Members' products are manufactured in a professionally responsible and safe manner until FDA

promulgates Good Manufacturing Practices (GMPs) for vapor products. In this regard, AEMSA has developed manufacturing standards for e-liquids which may be downloaded from our website at: http://www.aemsa.org/standards/. AEMSA is developing standards for E-liquid Components, ENDS Hardware Devices and Distribution/Retail. AEMSA supports reasonable, responsible and science-based regulation of e-liquids and vapor devices.

II. Summary of Request

Name of Regulation: 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; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products

Federal Register: 81 Fed. Reg. 28973 - 29106 (May 10, 2016)

Agency/Docket Number: Docket No. FDA-2014-N-0189

RIN: 0910-AG38

Document Number: 2016-10685

CFR: 21 CFR §§ 1100, 1140, 1143

Brief Description of Concern	Proposed Solution
The Deeming Rule prohibits vapor product innovation and safety improvements without FDA premarket review.	The Deeming Rule should be modified or, at a minimum, FDA should issue new guidance, permitting post-August 8, 2016 product modifications and continued innovation designed to address safety concerns without the need for immediate premarket review.
The Deeming Rule prohibits vapor product manufacturers from making truthful and non-misleading claims without FDA Modified Risk Tobacco Product (MRTP) review.	The Deeming Rule should be modified or, at a minimum, FDA should issue new guidance, permitting vapor companies to make truthful, non-misleading claims that their products do not contain harmful substances, and do not contain or generate smoke or tar, without having to go through the MRTP authorization process.
The Deeming Rule extends the tobacco product free sample ban to vapor products.	The Deeming Rule should be modified or, at a minimum, FDA should issue new guidance, permitting vapor companies to provide free samples of products to adult consumers,

	including taste testing at vape shops and other venues where consumers are age-verified.
The Deeming Rule extends the burdensome Premarket Tobacco Product Application (PMTA) requirement to all vapor products, which will ultimately eliminate most of the U.S. vapor industry.	The Deeming Rule should be modified or, at a minimum, FDA should issue new guidance that appropriately considers the existing data on the relative safety of vapor products compared to cigarettes to reduce the PMTA burden on individual manufacturers.

We describe the bases for our concerns and reasoning for our proposed solutions below.

III. FDA Docket No.: FDA-2017-N-5095

1. Is the regulation still current, or is it outdated or unnecessary is some way?

a. Have there been advancements and innovations in science, technology, or FDA or industry practice, or any other changes that suggest repeal of or modification to the regulation may be warranted or appropriate?

FDA has considerable discretion under its deeming authority to enforce the requirements of the Tobacco Control Act in a manner to achieve meaningful burden reduction for the vapor industry while allowing the Agency to accomplish its public health mission and fulfill its statutory obligations. In this regard, there are several aspects of the Deeming Rule that have become outdated or unnecessary, and that warrant immediate replacement or modification, based on advancements in technology and available scientific data on vapor products. Specifically, the rule (1) prohibits product innovation and prevents manufacturers from making safety improvements (2) prohibits manufacturers from making truthful and non-misleading claims about the health risks and composition of their products and (3) bans free samples to adult consumers. As discussed herein, based on new data about the safety of vapor products and their impact on the overall public health (i.e., population effects) we request FDA either modify the Deeming Rule or, at a minimum, issues new guidance documents as described herein.

i.) The Deeming Rule Prohibits Vapor Product Innovation and Should be Modified to Allow Safety Improvements Without FDA Premarket Review

Unlike traditional combusted tobacco products, advancements and innovations in 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. Accordingly, we

request the Deeming Rule be modified or, at a minimum, FDA issue new guidance, permitting post-August 8, 2016 product modifications and continued innovation designed to address safety concerns without the need for immediate premarket review.

In the Deeming Rule FDA chose not to amend the February 15, 2007 "grandfather date" for deemed products. Any tobacco product that was commercialized before the grandfather date may remain on the market without obtaining FDA pre-market authorization. However, manufacturers of "new tobacco products" must obtain such authorization. Moreover, because there are no known grandfathered vapor products, the only viable pre-market pathway is the PMTA, which is significantly more onerous than the Substantial Equivalence (SE) and SE Exemption pathways, and is estimated to cost millions of dollars.[1]

Pursuant to the Deeming Rule's compliance policy, which was recently extended by FDA guidance[2], the deadline to submit PMTAs for non-combustible tobacco products (like vapor) that were on the market as of August 8, 2016 is now August 8, 2022. While this extension is welcome, the compliance policy only effects products on the market prior to the effective date of the rule; new vapor products intended to be introduced *after* August 8, 2016 must *first* obtain PMTA authorization. The effect of this is that innovation is completely prohibited – manufacturers cannot modify their existing products in any way, even to make them safer or less harmful, as that would result in creating *new* products that need FDA authorization.

Undoubtedly, the desire to freeze the vapor market in this manner is based on the notion that all tobacco products are equally harmful and that, therefore, "innovation" can only make such products worse (i.e., more harmful or addictive). While this may be valid for combustibles like cigarettes, this could not be further from the truth for vapor products, which even FDA acknowledges are significantly less harmful than cigarettes. Indeed, in the Deeming Rule itself,

---

[1] The PMTA requires manufacturers to submit, inter alia, substantial amounts of information for each new tobacco product showing that marketing the product is "appropriate for the protection of public health." This "population effects" standard requires FDA to take into account the product's impact on the population as a whole, including the likelihood that people will stop using tobacco products (i.e., cessation), as well as start using them (i.e., initiation). 21 U.S.C. § 387j(c).

[2] *See* FDA Guidance for Industry, Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule, available at: https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM557716.pdf.

(continued …)

and more recently in Commissioner Gottlieb's announcement[3], FDA recognizes that using vapor products likely presents far less risk than smoking cigarettes, and that individuals switching from combustible tobacco products to vapor products may significantly reduce their harm.[4] The Agency also recognized that the availability of vapor products could potentially lead to increased smoking cessation rates in this country and ultimately reduce tobacco-related disease and death.[5] These conclusions are consistent with a growing body of scientific research, both in the United States and abroad, finding that vapor products are substantially less harmful than combustible tobacco products.

Moreover, advancements and innovations in vapor science and technology have significantly improved the safety of the products over the years. Innovative small businesses transformed the rudimentary first-generation "cigalike" e-cigarettes into advanced vaporizers that are better designed and incorporate numerous safety features including, but not limited to:

- Control circuits with temperature control/limiting capability;
- Microprocessors used to monitor and adjust the power and heat delivered, ensuring consistent aerosol delivery;
- Over/under-charge and short-circuit protections (internal on device circuit boards);
- "Smart charging" ability using cell phone technology which stops charging current flow to battery when fully charged;
- Newer refillable tanks/atomizers do not contain the cartomizer filler material found in cigalikes, which has the potential to melt/char if heated after the e-liquid is consumed;

---

[3] *See* Protecting American Families: Comprehensive Approach to Nicotine and Tobacco, available at: https://www.fda.gov/NewsEvents/Speeches/ucm569024.htm.

[4] *See* FDA Response to Comment 118 of the Deeming Rule, 81 Fed Reg. at 29030 ("FDA recognizes that completely switching from combusted cigarettes to ENDS may reduce the risk of tobacco-related disease for individuals currently using combusted tobacco products, given the products' comparative placement on the continuum of nicotine-delivering products.").

[5] *See* FDA Response to Comment 144 in preamble to Deeming Rule. 81 Fed. Reg. at 29037 ("We recognize that there is emerging data that some individual smokers may potentially use ENDS to transition away from combustible tobacco products").

(continued …)

- "Boost circuits" which help to ensure consistent aerosol output by maintaining the heat level, as well as offering adjustable airflow features allowing the user to customize their experience and prevent potential "dry puff"; and

- For cigalikes, airflow sensors that detect when the user is using the device, which turns the battery on to provide power to the vaporizer.

The Deeming Rule's August 8, 2016 market freeze prohibits all such future innovation and even modifications to products with known safety concerns. This does nothing but harm the public health. Manufacturers should be allowed to reformulate their e-liquids to remove potentially harmful ingredients, incorporate device design features discussed at FDA's public workshop for *Battery Safety Concerns in Electronic Nicotine Delivery Systems*, or use new components that are compliant with the upcoming UL 8139 standard[6], without having to spend potentially millions of dollars on PMTAs that have no guarantee of approval.

Thus, we request the Deeming Rule be modified or, at a minimum, FDA issue new guidance, permitting post-August 8, 2016 product modifications and continued innovation of e-liquid and ENDS hardware devices designed to address safety concerns without the need for immediate premarket review.

ii.) The Deeming Rule Prohibits Vapor Product Manufacturers from Making Truthful and Non-Misleading Claims and Should be Modified to Permit Factual Statements Without FDA Modified Risk Tobacco Product Review

As noted, although there is a substantial evidence supporting that vapor products are less harmful than cigarettes and other combusted tobacco products, manufacturers are prohibited from making any such claims without modified risk tobacco product (MRTP) authorization from FDA. Specifically, pursuant to Section 911 of the Tobacco Control Act, 21 U.S.C. § 387k, a MRTP is a tobacco product that represents in its label, labeling, or advertising, either implicitly or explicitly, that (i) it presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products; (ii) it or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; (iii) it or its smoke does not contain or is free of a substance or (iv) uses the descriptors "light," "mild," "low," or similar descriptors.

Obtaining MRTP authorization for a vapor product is even more difficult than getting PMTA marketing authorization. Like a PMTA, MRTP applications require FDA to consider both

---

6 *See* UL Develops Safety Requirements for E-Cigarette Electrical Systems, https://industries.ul.com/blog/ul-develops-safety-requirements-for-e-cigarette-electrical-systems.

individual consumer and population-wide risks. But MRTP applications require the manufacturer to demonstrate *more* than appropriateness for the protection of public health; they must demonstrate instead that the product, as actually used by consumers, will "significantly reduce harm and the risk of tobacco-related disease to individual tobacco users," and "benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products."[7] 21 U.S.C. § 387k(g)(1).

Moreover, getting MRTP authorization to make simple, factual statements that a vapor product does not contain tobacco or specific harmful substances, or does not produce smoke or tar, for example, is virtually impossible, despite the growing body of evidence supporting the reduced harm of vapor compared to cigarettes and FDA's acknowledgment of the "continuum of risk" of tobacco products. These kinds of claims fall under the "Special Rule for Certain Products" in Section 911(g)(2) of the Act, which requires, among other things, "testing of actual consumer perception" which "shows that, as the applicant proposes to label and market the product, consumers will not be misled into believing that the product (i) is or has been demonstrated to be less harmful; or (ii) presents or has been demonstrated to present less of a risk of disease than 1 or more other commercially marketed tobacco products[.]"

In other words, to truthfully state that a vapor product does not produce smoke or tar, a manufacturer would have to prove – through actual perception studies – that such statements do *not* cause consumers to believe that the product has been proven to be less harmful.[8] This, of course, ignores the reality of tobacco harm reduction and the purpose of making reduced exposure claims.

The MRTP authorization requirement is rooted in the belief that all tobacco products are harmful and that relative safety is a myth. In the Deeming Rule, FDA concludes that the MRTP process is needed to guard against misleading health claims, like those the Agency says

---

[7] FDA's MRTP guidance established minimum scientific standards for demonstrating that a product results in a substantial reduction of morbidity or mortality in individual tobacco product users (e.g., long-term epidemiological studies), including validated biomarkers, intermediate clinical endpoints, and other appropriate outcome measures. In addition, FDA provided guidelines for post-market studies and surveillance addressing assessment of both regular and long-term health outcomes, consumer perception of harm reduction, and impact on tobacco product cessation and uptake. To date, FDA has not approved the marketing of any MRTPs.

[8] Smoke and tar are not produced because e-liquids do not contain tobacco leaf and are not combusted; when used as intended the heated e-liquid is vaporized into an aerosol that does not contain particulate matter (tar) or many of the carcinogens and harmful substances seen in traditional tobacco products.

(continued …)

characterized the marketing of traditional tobacco products over the span of many decades (e.g., cigarettes that made "light," "mild," or "low" claims were eventually shown to still pose significant health risks[9]). The vapor industry, which only emerged in the last 10 years, does not have such a history and should be allowed to truthfully discuss the potential benefits of their products with consumers. *See, e.g.*, 81 Fed. Reg. at 28,987. We further note that the Tobacco Control Act inexplicably permits smokeless tobacco products (e.g., snus, chewing tobacco) to use phrases like "does not produce smoke," "smokefree," "smoke-free," "without smoke," "no smoke," or "not smoke" it their labeling and advertising *without* MRTP authorization. 21 U.S.C. § 387k(b).

The prohibition on truthful communication has not only likely played a role in the increasing number of Americans who erroneously believe that vapor products are either as harmful or *more* harmful that cigarettes,[10] but is a violation of the First Amendment of the Constitution, which protects commercial speech. Where the federal government restricts commercial speech, it must demonstrate that: (i) the regulated speech is not misleading; (ii) the governmental interest is substantial; (iii) the restriction directly advances the governmental interest; and (iv) the regulation is not more extensive than is necessary to serve that interest.[11] For the reasons noted above, the MRTP process as applied to vapor products captures commercial and non-commercial speech that is clearly *not* misleading, and fails to directly advance any purported government interests (which focus on the impact of traditional tobacco products). FDA also has less intrusive options to advance any interests in approving modified risk claims, such as the use of disclaimers to prevent any purported consumer confusion or simply verifying any tests conducted by the manufacturer to confirm that a certain substance has been detected in low amounts or is completely absent from the product.

In short, new data on the health and safety risks of vapor products and how consumers are using them to transition away from smoking has rendered the MRTP provision of the Tobacco Control Act obsolete and in violation of the First Amendment. **Accordingly, we request the Deeming Rule be modified or, at a minimum, FDA issue new guidance, permitting vapor companies to make truthful, non-misleading claims that their products do not contain**

---

[9] *See* Light, Low, Mild or Similar Descriptors, available at: https://www.fda.gov/TobaccoProducts/Labeling/Labeling/ucm2023661.htm.

[10] *See* More Americans Believe E-Cig's As Harmful As Cigarettes, by F. Ardito, available at: http://www.vapor-news.com/2016/10/28/american-adults-harmful-ecigs/.

[11] *See Central Hudson Gas & Electric Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980).

harmful substances, and do not contain or generate smoke or tar, without having to go through MRTP authorization process.

iii.) The Deeming Rule Extends the Tobacco Product Free Sample Ban to Vapor Products and Should be Modified to Permit Free Sampling of Vapor Products by Adult Consumers

The Tobacco Control Act prohibits manufacturers and retailers from distributing free samples of tobacco products, other than free samples of smokeless tobacco distributed in "qualified adult-only facilities." 21 U.S.C. § 387a-1(a). The Deeming Rule unnecessarily extends the free sample ban to vapor products and should be modified to permit free samples, including product taste testing, to adult consumers. 81 Fed. Reg. at 28,976; 21 C.F.R. § 1140.16. This free sample ban includes the sampling of e-liquids by customers in vape shops and at other events that are restricted to adult consumers. 81 Fed. Reg. at 29,054. In the preamble to the Deeming Rule, FDA justifies the total ban on free samples on preventing youth access to vapor products. 81 Fed. Reg. at 28,986-87. That interest ceases to exist, however, if free samples are limited to adult consumers.

Allowing adult customers to sample various e-liquids before purchase is integral to the marketing of those products. Consumer surveys demonstrate that flavors, including flavor variety, is a primary reason why vapers continue to vape and move away from combustible tobacco-products.[12] Allowing adult consumers to test various flavors prior to purchase is, therefore, an important part for retaining customers and business and for tobacco harm reduction.

Distributing free samples is a form of non-misleading speech protected by the First Amendment. FDA does not have a substantial interest in prohibiting access to free samples by adult consumers, nor does a complete ban directly advance the government's stated interests. There are also more narrow options available to FDA to advance the government's interest in preventing youth access while still allowing vape shops and others to market using free samples. FDA could have simply restricted free sampling to vape shops and other venues that are subject to minimum age and identification requirements.

We note that under the Deeming Rule, retailers are required to verify that a customer is 18 years or older before selling an e-liquid. 81 Fed. Reg. at 29,057. Moreover, the Deeming Rule prohibits the sale of vapor products through vending machines "unless the vending machine is located in a facility where the retailer ensures that individuals under 18 years of age are

---

[12] *See* Survey Shows Adults Who Use E-Cigarettes To Quit Smoking Prefer Supposedly Juvenile Flavors, by J. Sullum, available at: https://www.forbes.com/sites/jacobsullum/2014/07/17/survey-shows-adults-who-use-e-cigarettes-to-quit-smoking-prefer-allegedly-juvenile-flavors/#23eb2c9c8fc1.

prohibited from entering at any time." Id. at 28,976. The same approach should apply to free samples.

Accordingly, we request the Deeming Rule be modified or, at a minimum, FDA issue new guidance, permitting vapor companies to provide free samples of products to adult consumers, including taste testing at vape shops and other venues where consumers are age-verified.

2. **Have regulated entities had difficulties complying with the regulation? If yes, identify what entity or entities have had such difficulties and the nature of the difficulties.**

   a. **The Burdensome PMTA Requirement Will Eliminate Most of the Vapor Industry and Should be Modified to Consider Existing Data on The Relative Safety of Vapor Products to Reduce the Burden on Individual Manufacturers**

Vapor product manufacturers are facing severe difficulties complying with the PMTA requirement that applies to all such products, and many will likely either go out of business or cease marketing in the United States unless FDA reduces and clearly identifies the data needed to demonstrate that a product is "appropriate for the protection of the public health". While AEMSA appreciates FDA's recent announcement extending the PMTA deadline to August 8, 2022 for vapor products on the market as of August 8, 2016, the amount of data needed to demonstrate that a vapor product meets the public health standard, including human clinical and long-term data[13], is so voluminous and costly to produce that requiring PMTAs for all vapors products (none of which are grandfathered or can take advantage of the SE reporting process) will effectively ban or virtually eliminate such products from the market. Indeed, FDA admitted in the Deeming Rule that between 95-97% of vapor product manufacturers (including vape shops that manufacture) would cease to exist because of the PMTA requirement.

Accordingly, we request the Deeming Rule be modified or, at a minimum, FDA issue new guidance, that appropriately considers the existing data on the relative safety of vapor products compared to cigarettes to reduce the PMTA burden on individual manufacturers.

---

[13] *See* FDA Draft Guidance for Industry, Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (May 2016), available at: https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM499352.pdf.

* * *

AEMSA appreciates the opportunity to submit these comments, and would be glad to discuss with FDA at its earliest convenience.

Sincerely,

Scott Eley
President
American E-Liquid Manufacturing Standards Association

On behalf of AEMSA members:

NicQuid	Mister E-Liquid	Giant Vapes
Firebrand	Molecule	Upper Limits Midwest
The Vapor Bar	NicVape	The Vape Shop
Texas Select	Purilum	Demand Vape
Chuckin' Clouds	Saffire	The Vapor Shoppe
ECBlends	Tampa Vapor	SAEURvape
Eclipse	Vapor HQ	
Jvapes	Vandalia Mist	
Mad Vapes	Flavourart	