VAPOR TECHNOLOGY ASSOCIATION

December 20, 2018

Mitch Zeller, J.D.
Center Director
Center for Tobacco Products
Food and Drug Administration
Document Control Center
10903 New Hampshire Avenue
Building 71, Room G335
Silver Spring, MD 20993-0002

Matthew R. Holman, Ph.D.
Director, Office of Science
Center for Tobacco Products
Food and Drug Administration
Document Control Center
10903 New Hampshire Avenue
Building 71, Room G335
Silver Spring, MD 20993-0002

Re: Docket No: FDA-2017-N-5095
Subject: Tobacco Products Regulatory and Information Collection Requirements

Dear Director Zeller and Dr. Holman:

I am writing to you on behalf of the Vapor Technology Association (VTA). As you are aware, VTA represents the leading manufacturers of open and closed system devices and leading manufacturers of e-liquids, along with distributors, suppliers and hundreds of brick and mortar vape shops around the United States.

For the reasons set forth in this letter, we are very concerned about the Food and Drug Administration's (FDA) rapidly approaching compliance deadline for submitting harmful and potentially harmful constituent (HPHC) listings under section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act (FFDCA or Act) for finished, deemed tobacco products on the market on August 8, 2016. Accordingly, VTA is respectfully requesting that the compliance date be extended until at least one year after FDA issues a final guidance or final regulation providing recommendations or requirements for HPHC listings for deemed vapor products.

Moreover, because we represent so many small tobacco products manufacturers ("Small Manufacturers"), we would request that the deadline for Small Manufacturers extends at least an additional twelve (12) months beyond that generally applicable extended compliance date for Small Manufacturers to comply.[1]

[1] A "small tobacco product manufacturer" is defined as one that "employs fewer than 350 employees." 21 U.S.C. § 387(16).

VTA asserts that it would put the proverbial cart before the horse to require HPHC submissions before the final guidance for such submissions is even available. As you know, the current compliance date for submission of section 904(a)(3) HPHC listings for deemed finished tobacco products on the market on August 8, 2016, is November 8, 2019. In the preamble to the final deeming rule, FDA stated that it "intends to issue a guidance regarding HPHC reporting under section 904(a)(3)" in advance of the compliance date.[2] As of today, FDA has not issued any such guidance, much less a *draft* of such guidance.

Manufacturers need both clarity and the opportunity to comply with any and all required submissions of HPHC listings for finished, deemed products. To that end, FDA must issue final guidance (or, preferably, a final regulation) that both specifies the constituents and deemed product categories for which the Agency will require HPHC listings and identifies the standardized testing methodologies that have been validated for this purpose for each such constituent for each such product category.

There is precedent for VTA's request. In March 2012, FDA issued guidance *narrowing* the constituents and categories of originally regulated products for which the Agency would enforce the section 904(a)(3) HPHC listing requirements. At the same time, FDA *extended* the statutory compliance date by 6 months for Small Manufacturers and by 3 months for all others. The guidance therefore gave small companies approximately 9 months of lead time to test and report HPHCs in accordance with the guidance's recommendations.

More importantly, today there is a stronger case for greater clarity and significantly more time to comply. Our investigation has revealed that validated *standardized* testing methodologies and *standard* equipment for evaluating the levels of HPHCs in several categories of deemed products simply does not exist today. Also, the enormous number of unique vapor products on the market that would require HPHC testing and submitted listings so greatly outnumber the originally regulated products, that FDA must consider a different timetable.

Very simply, there are too few laboratories and qualified personnel to handle the significant number of newly deemed products in the vapor sector alone. Moreover, existing labs will not have enough time to expand or develop the required expertise, much less acquire the necessary equipment, to properly conduct this testing. Thus, VTA's member companies desiring to comply with FDA regulations simply will not be able to do so because they will not be able to access the requisite laboratory space. Given the number of companies and products that will be subject to this HPHC requirement, the laboratory capacity concerns that arose in 2012 will seem like nothing during this next required round of HPHC testing for deemed products.

Importantly, special relief needs to be afforded to Small Manufacturers since virtually all such manufacturers will have to rely on outside laboratories and will not be able to conduct any such testing in house. Congress acknowledged this fact in including special provisions for Small Manufacturers in section 915 of the Act. The Act provided that by April 1, 2013, FDA must issue

[2] 81 Fed. Reg. 28,974, 28,980 (May 10, 2016).

regulations under section 915 requiring the "testing and reporting of tobacco product constituents, ingredients, and additives, including smoke constituents" of marketed tobacco products. Again, FDA has not yet published even a proposed rule under this provision. Congress devoted a substantial amount of section 915 to special provisions affording Small Manufacturers additional time for compliance with these related testing requirements.

Importantly, as you may be aware, FDA is required under section 915(d)(1) to promulgate special compliance dates applicable to Small Manufacturers, including setting the initial compliance date for Small Manufacturers as the later of two years after the regulation's promulgation or the generally applicable compliance date. Section 915(d)(2)(A) further requires FDA to afford Small Manufacturers a combined four-year period from the initial compliance date to test and report on their full product lines. In addition, section 915(e) requires FDA to promulgate regulations providing that Small Manufacturers will be considered "not in violation" of the testing and reporting requirements if they can establish that their reporting delays are attributable to limited laboratory capacity.

Also, it is imperative that HPHC testing be standardized, something that cannot happen until FDA fully implements section 915 testing and reporting regulations. Without clear guidance on this point, the data submitted by companies for a wide variety of products will not be meaningfully or scientifically comparable. In such circumstance, the utility of any data produced and HPHC reports section 904(a)(3) will be circumspect.

One of the central reasons that VTA is strongly recommending that FDA consider extending the HPHC testing deadline, and refine the specific requirements before requiring testing, is that the enormous cost and effort will not be justified if FDA is not prepared to actually release the information submitted. We raise this issue because, even though section 904(d) requires the publication and display of HPHC data – in an understandable form which is not misleading to a lay person – FDA has not disclosed the HPHC data previously gathered six years ago for tobacco products. Presumably, FDA has not determined a way to provide those data in a format that is understandable and not misleading to the public. Hence, requiring testing of ENDS products in the absence of standardized methods and equipment will likewise fail to produce understandable and nonmisleading information.

FDA should not impose additional regulatory burdens on industry that do not have an actual public health purpose or scientific foundation. Based on these considerations, FDA should strongly consider delaying enforcement of the section 904(a)(3) HPHC listing requirements for finished, deemed tobacco products in the absence of final section 915 regulations. Regardless, the Agency should not exacerbate these burdens on industry by enforcing the current compliance date for section 904(a)(3) HPHC listings for deemed products. Even were FDA to issue final guidance (or a final regulation) in the very near term, it is undeniable that industry generally and Small Manufacturers in particular would lack appropriate lead time to implement FDA's expectations for these submissions by November 8, 2019. Certainly, a small number of companies may be able to cobble together testing results that may or may not match what FDA is actually seeking, but FDA's enforcement of the regulations must permit all companies a fair and reasoned opportunity to comply with FDA's regulations.

At the end of the day, there are innumerable factors that demonstrate why FDA would be acting prudently, fairly, and lawfully if the Agency extended the HPHC compliance deadline. These reasons are described above but are fairly summarized as follows:

- the enormous number of deemed ENDS products for which testing is required;
- the limited laboratory space that will prevent any reasonable attempts at compliance;
- the lack of protocols and methods for measuring HPHCs, not to mention equipment, for deemed ENDS products and the emitted vapor;
- the lack of guidance or regulations on specifically what kind of HPHC testing will be required or accepted; and
- the apparent lack of any plan for disclosure of submitted HPHC testing.

Given all of these factors, VTA respectfully requests that (a) FDA extend the HPHC listing compliance date for finished, deemed ENDS products which were the market on August 8, 2016, until at least one year after issuance of a final guidance (or regulation) on HPHC listing requirements for these products, and (b) grant Small Manufacturers at least an additional 12 months beyond the generally applicable extended compliance date to comply.

As always, we appreciate your thoughtful consideration of these challenging and complex issues.

Warmest regards,

Tony Abboud
Executive Director
On behalf of VTA

cc: VTA Board of Directors