DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

JUN 16 2016

The Honorable Ron Johnson
Chairman
Committee on Homeland Security and Governmental Affairs
United States Senate
Washington, D.C. 20510-6250

Dear Mr. Chairman:

Thank you for your letters of May 17, and June 6, 2016, regarding the Food and Drug Administration's (FDA or the Agency) recently finalized rule, *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* (deeming final rule). We appreciate your interest in the deeming final rule, and in particular, your interest in how the rule will affect public health and small businesses.

Tobacco use is a significant public health threat that is particularly affecting youth. While there has been a significant decline in the use of traditional cigarettes among youth over the past decade, their use of other tobacco products continues to climb. A recent survey supported by FDA and the Centers for Disease Control and Prevention shows current e-cigarette use among high school students has increased from 1.5 percent in 2011 to 16 percent in 2015 (an over 900 percent increase) and hookah use has risen significantly. In 2015, three million middle and high school students were current e-cigarette users, and data showed high school boys smoked cigars at about the same rate as cigarettes.

The deeming final rule extends FDA's tobacco product authorities to additional categories of products that meet the statutory definition of a tobacco product, including electronic nicotine-delivery systems, or ENDS (e.g., e-cigarettes, vape pens, and others), cigars, pipe tobacco, gels, hookah (waterpipe) tobacco, and future tobacco products. Once the provisions of the final rule are in effect, manufacturers, importers, distributors, and retailers of such tobacco products must comply with the applicable provisions related to tobacco products in the Federal Food, Drug, and Cosmetic (FD&C) Act and FDA regulations, including:

- Registering manufacturing establishments and providing product listings to FDA;
- Reporting ingredients, and harmful and potentially harmful constituents;
- Premarket review and authorization of new tobacco products by FDA;
- Placing health warnings on product packages and advertisements;
- Not allowing the distribution of free samples; and
- Not selling modified risk tobacco products (including those described as "light," "low," or "mild") unless authorized by FDA.

In addition, there are several provisions aimed at restricting youth access to tobacco products,

including:

- Not allowing covered tobacco products to be sold to persons under the age of 18 years (both in-person and online);
- Requiring age verification by photo ID; and
- Not allowing the selling of covered tobacco products in vending machines (unless in an adult-only facility).

FDA recognizes the concerns that small businesses may have with complying with the requirements in the deeming rule. In the proposed deeming rule, FDA specifically requested comment on the ability of smaller manufacturers of newly deemed tobacco products to fully comply with the requirements and how FDA might be able to address those concerns. After considering the comments and as stated in the preamble to the rule, FDA intends – among other things – to grant small-scale tobacco product manufacturers additional time to comply with certain provisions of the regulation. For purposes of this compliance policy, FDA generally considers a "small-scale tobacco product manufacturer" to be a manufacturer of any regulated tobacco product that employs 150 or fewer full-time equivalent employees and has annual total revenues of $5,000,000 or less.

FDA understands that newly-regulated entities, including small businesses, will need assistance in complying with the FD&C Act and FDA regulations. The Agency is committed to providing this assistance. For example, on May 5, 2016, concurrent with the announcement of the final rule, FDA announced the availability of several other regulatory documents that provide additional clarity, instructions, and FDA's current thinking on issues specific to newly-deemed products. These accompanying documents include:

- Premarket Tobacco Product Applications (PMTAs) Draft Guidance for ENDS: This guidance, when final after public comment, is intended to assist persons submitting PMTAs for ENDS. The draft guidance discusses general procedures for submitting a PMTA and the type of information FDA believes should support a PMTA. The Agency expects this information will help companies to more efficiently produce PMTAs.
- Tobacco Product Master File (TPMF) Guidance: This final guidance provides recommendations to industry on TPMFs. TPMFs are used to permit the person that owns the TPMF to authorize other persons to rely on information in the TPMF to support a submission to FDA without the TPMF owner having to disclose information to other persons. These files typically contain trade secret and/or confidential commercial information that the TPMF owner does not wish to disclose to the applicant or to the public. The ability to rely on TPMFs to support applications may be especially beneficial for smaller businesses whose products contain materials supplied by contract manufacturers or other entities.
- Small Entity Compliance Guide for Deeming: This guide is intended to help small businesses understand and comply with the final deeming rule.

In addition to the documents listed above, FDA has provided, and will continue to provide, additional assistance to newly-regulated entities, including small businesses. Within the last month, FDA posted six compliance training webinars about the deeming final rule and hosted one live webinar where retailers could ask questions about the rule. FDA plans to add additional

webinars to our website to assist industry. FDA also has dedicated additional resources to staff the Center for Tobacco Products' Office of Small Business Assistance. This Office has responded to more than 500 questions since the deeming final rule published and continues to respond to questions from industry, including small businesses.

The specific questions in your letter are repeated in bold type below, followed by our responses.

1. **The final rule notes that the FDA does "not currently have sufficient data about e-cigarettes and similar products to fully determine what effects they have on the public health." Further, the final rule states that "comments were divided on the safety and toxicity of e-liquids, e-cigarettes, and the exhaled aerosol."**

    a. **Will the FDA issue a revised rule if there is sufficient data that finds that e-cigarettes are a safer alternative to traditional cigarettes? Please explain.**

The final deeming rule is primarily a foundational rule, which extended FDA's tobacco product authorities to additional categories of products that meet the statutory definition of a tobacco product, including e-cigarettes. The rule is the *beginning* of the process of the regulation of e-cigarettes, and the other products covered in the final rule. That regulatory framework will evolve over time as we learn more about the products. Now that FDA will finally have regulatory authority over these previously unregulated products, the Agency can expand its knowledge base regarding these products. Once the products are subject to FDA's tobacco authorities under the FD&C Act, FDA will be able to obtain critical information regarding the health risks of newly deemed tobacco products, including information derived from ingredient listing submissions and reporting of harmful and potentially harmful constituents (HPHCs). Armed with the answers to important questions about e-cigarettes and how they are made, marketed and used, we will be able to assess over time whether, how, and to what extent they are beneficial or harmful and to whom. In addition, subjecting e-cigarettes to FDA's tobacco product authorities will give manufacturers an incentive to conduct research and submit data to establish any potential public health benefit of e-cigarettes.

There are distinctions in the hazards presented by various nicotine-delivering products. Cigarette smoking is the major contributor to the death and disease attributable to tobacco use. Given this, some have advanced the view that certain new non-combustible tobacco products (including ENDS products such as e-cigarettes) may be less hazardous, at least in certain respects, than combustible products, given the known carcinogens in smoke and the dangers of secondhand smoke.

Scientific evidence may demonstrate that certain products are less harmful than others at an individual level, but the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) directs FDA to also take into account the impact on the health of the population as a whole, including both users and non-users of tobacco products, in making regulatory decisions about these products. E-cigarettes could benefit public health if they encourage people who would otherwise not quit smoking to stop smoking altogether, while not encouraging youth or others to start use of tobacco products or encouraging former users to relapse back to tobacco use. On the other hand, e-cigarettes could be a detriment to public health if they re-normalize smoking, encourage youth to initiate smoking, or prompt users to continue or to escalate to cigarette use—

in effect, reversing the meaningful progress tobacco control initiatives have achieved to date. Other reported e-cigarette risks include dermal exposure to nicotine, child poisoning, and physical harm from defective products (such as exploding batteries).

Scientific evidence will inform FDA's regulatory actions with respect to e-cigarettes. To further that aim, FDA has made a significant investment in regulatory science research to answer the fundamental questions about e-cigarettes related to product safety, patterns of use, perceptions of the products, and overall benefit and risk at the population level. FDA is committed to using an evidence-based approach to the application of the principles of harm reduction to tobacco regulatory policy.

Finally, it is important to note that the general effect a product category may have on public health is not necessarily true for all products in that category. Even if ENDS in general are shown to be beneficial, regulation of individual products through the premarket review process will allow FDA to identify problematic products that may raise unique concerns. For example, individual products may raise special concerns about youth initiation, or may contain harmful constituents not found in the majority of ENDS products.

b. How is the FDA's regulation of e-cigarettes not a premature restriction on an industry given the FDA's admission that it does not have "sufficient data" about e-cigarettes to determine the effects on the public's health?

Again, it is critically important to understand that the final deeming rule is primarily a foundational rule, which extended FDA's tobacco product authorities to additional categories of previously unregulated products that meet the statutory definition of a tobacco product, including e-cigarettes. The rule is the *beginning* of the process of the regulation of e-cigarettes, and the other products covered in the final rule.

All tobacco products are potentially addictive and some ENDS may deliver as much nicotine as combustible cigarettes or smokeless products. The Surgeon General has stated that adolescents appear to be particularly vulnerable to the adverse effects of nicotine on the central nervous system. The final deeming rule, along with the minimum age restrictions and health warning requirements, is an important step toward addressing the rise in tobacco product use among youth.

Although FDA noted in the proposed rule that we do not currently have sufficient data about e-cigarettes and similar products to fully determine what effects they have on the health of the population as a whole, the Agency identified concerns regarding the toxicants in e-liquid and the exhaled aerosol, and the nicotine delivery from e-cigarettes.

FDA's regulatory tools as applied to newly deemed tobacco products (including e-cigarettes), will help to protect consumers by subjecting all tobacco products to certain requirements. For example, although there is currently variability in the concentrations of chemicals in e-liquids, FDA oversight of the constituents in e-liquids and ENDS will help to ensure quality control over the types and quantities of chemicals being aerosolized and inhaled.

Now that FDA will have regulatory authority over these previously unregulated products, and armed with the answers to important questions about e-cigarettes and how they are made, marketed and used, we will be able to assess over time whether, how, and to what extent they are beneficial or harmful and to whom.

2. Some stakeholders claim that the FDA's rule on e-cigarettes will stifle innovation and result in the closure of many small businesses that create and sell e-cigarette products.

a. Did the FDA determine how many e-cigarette businesses will be affected by the rule? If not, why?

Yes, FDA estimated the number of e-cigarette businesses that will be affected by the rule and these estimates are included in the Regulatory Impact Analysis (RIA), which may be accessed at: *www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/ucm500249.htm.*

b. If so, please provide that data.

The RIA includes information about the number of manufacturers, importers, and retailers of ENDS products affected by the final deeming rule on pages 68-73. The baseline number of manufacturers and importers of ENDS products is uncertain.[1] Some public comments referenced the Smoke-Free Alternatives Trade Association in stating that there are over 1,200 ENDS manufacturers. Many of these manufacturers, however, are believed to be smaller, informal participants in this market; in describing the current landscape in the ENDS industry, an industry survey respondent wrote, "Too many companies are making e-liquid in their kitchens/bathrooms."[2] We do not have reliable counts on these informal producers but we expect that few if any of them will continue to manufacture after this final rule takes effect.[3] We therefore restricted our analysis to those we identified as the formal manufacturers in this market. Based on logo counts from trade association websites and information from FDA listening sessions, we estimated that there are 168 to 204 formal manufacturers of ENDS products; we used this range for the quantitative analysis. We acknowledge that the total, including informal manufacturers, may be far greater. Using the same logo counts from trade association websites and information from FDA listening sessions, we also estimated that there are 14 importers of ENDS products.

In addition to establishments specifically engaged in manufacturing, retailers may meet the definition of tobacco product manufacturers if they manufacture, fabricate, assemble, process, or label a tobacco product. Vape shops that engage in e-liquid manufacturing and mixing are perhaps the most prominent example. Based on public comments, news articles, and industry

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[1] ENDS products that do not contain tobacco do not satisfy the definition of "tobacco products" in the Internal Revenue Code, and, therefore, are not subject to tax under the Internal Revenue Code. Accordingly, TTB does not collect information about the number of ENDS manufacturers and importers. The term "tobacco product" is defined differently in the IRC and the FD&C Act.

[2] Herzog, Bonnie, Jessica Gerberi, and Adam Scott. 24 March 2014a. "Tobacco Talk: Vapors/Tanks Driving Next Wave of E-Vapor Growth." Wells Fargo Securities.
http://www.vaporworldexpo.com/PDFs/Tobacco_Talk_Vapors_Tanks_%20March%202014.pdf

[3] The costs of exit by informal manufacturers are expected to be small due to low levels of investment in specialized capital and skills.

reports, we estimated that there are approximately 5,000 to 10,000 vape shops; we assumed that 70 percent of them, or 3,500 (=70%*5,000) to 7,000 (=70%*10,000), currently engage in manufacturing activities.[4]

In total, we estimated that between roughly 5,200 and roughly 10,200 ENDS businesses would be affected by the rule in some way.

c. Of the e-cigarette businesses that will be affected by the rule, how many of those businesses does the FDA predict will exit the market as a result of the new requirements?

The RIA includes a discussion of potential exit for e-cigarette businesses.

Some manufacturers or importers may cease to sell newly-deemed products in the U.S. rather than bear the cost of complying with this final rule. In particular, some low-volume cigar or ENDS manufacturers and importers may cease to offer their products in the U.S. We noted foreign producers may not necessarily cease to operate; rather, they may reduce the number of products they sell in the U.S. or cease to sell their products in the U.S. We did not estimate the amount of potential exit among manufacturers and importers.

As a result of this final rule, retailers who currently meet the definition of manufacturer may cease to engage in manufacturing activities. Although we did not estimated entity exit, we assumed that the proportion of vape shops that prepare their own mixtures for sale, as of the effective date, may fall (from the baseline proportion of 70% who currently mix as some part of their business) during the initial compliance policy period for submission and FDA receipt of PMTAs (i.e., 24 months from the effective date of the rule). To reflect uncertainty about the extent of the decline, we assumed that the share of vape shops that will continue to mix during the initial compliance policy period could drop to as low as 30% or could remain as high as 70%; thus, the number of businesses that we estimated will continue to mix during this period could be as low as 1,500 (=30%*5,000) or as high as 7,000 (=70%*10,000) shops. After this initial compliance policy period, we further assumed that many vape shops will continue to operate, with those that have not already switched to pure retailing doing so at this time.

3. Has the FDA considered the unintended consequences if decreased access to e-cigarettes leads to increased consumption of traditional cigarette and tobacco products? Please explain.

FDA received comments on the proposed deeming rule regarding the cost of PMTAs for newly deemed products and the effect that this requirement will have on cigarette smokers who are attempting to quit. Some comments disagreed with FDA's assertion that premarket review will enhance innovation, stating that the cost of submitting PMTAs is more of a business concern than competition with lower quality products. They claimed that the PMTA process would have the largest negative impact on open system apparatus, which some comments believed are the most popular with people who have achieved complete substitution from conventional cigarettes

[4] Burke, Don. 23 April 2015. "Trends & Insights in the Nicotine Delivery Category." Management Science Associates, Inc. Presentation at NATO Show. Accessed June 2015.

to e-cigarettes. The comment suggests that the result would be that newer e-cigarettes would not make it onto the market, driving up prices, and driving adult consumers back to conventional cigarettes.

The Tobacco Control Act provides for three specific marketing pathways for new tobacco products: Substantial Equivalence (SE), SE exemption, and PMTA. Through the PMTA pathway, FDA will ensure that only products that are shown to be appropriate for the protection of public health, a standard mandated by law, and are permitted to be marketed. Use of the PMTA pathway also will allow FDA to monitor product development and changes and to prevent more harmful or addictive products from reaching the market. The PMTA pathway will incentivize development of tobacco products that pose less risk to human health by limiting market access for more-risky competitor products. Furthermore, since the "appropriate for the protection of the public health" standard involves comparison to the general tobacco product market existing at the time of an application, FDA believes that, over time, the premarket authorities will move the market toward less-risky tobacco products.

A recently published paper by Friedman[5] looked at youth smoking rates in states that enacted early bans on sales of e-cigarettes to minors. The author concluded, based on state level combusted cigarette smoking data available through 2013, that the decline in adolescent smoking rates slowed in states that enacted restrictions on access to ENDS by minors before January 2013, relative to states that did not. Some have interpreted the results of the study as providing evidence that any policies that restrict access to e-cigarettes or regulate e-cigarettes could increase consumption of combusted tobacco products. However, the research has several limitations that are acknowledged in the study. First, the survey data used in the study, from the National Survey on Drug Use and Health, track changes in the prevalence of cigarette smoking but lack information available on e-cigarette use. As such, the study does not establish that youth switched directly from using ENDS to smoking combusted cigarettes after restrictions on sales of e-cigarettes to minors were enacted, only that the decline in prevalence of cigarette smoking slowed in states where such restrictions were enacted relative to states that did not. Second, the fact that the study examines a period very early on in the development of the market for ENDS products may also limit the inferences that can be drawn for substitution and dual usage patterns that will emerge as the market matures. Third, the "increase" in the prevalence of youth smoking is relative to what would have been predicted from ongoing trends; in both states that did and states that did not enact restrictions, the prevalence of youth smoking continued to decline, just at a slower rate in the states that enacted bans. Finally, given these issues, FDA acknowledges this paper as a first attempt to study potential impacts of youth ENDS access restrictions, but more research will be necessary to explore the potential effects of this rule on product switching or dual usage.

FDA also considered the increased access to e-cigarettes by young people, with our own data making clear that there has been a 900 percent increase in youth use of e-cigarettes between 2011 and 2015. The final deeming rule is primarily a foundational rule, which extended FDA's tobacco product authorities to additional categories of previously unregulated products that meet the statutory definition of a tobacco product, including e-cigarettes. What we

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[5] Friedman, A. S., "How does Electronic Cigarette Access Affect Adolescent Smoking?," *Journal of Health Economics*, 44:300-308, 2015, available at *http://www.sciencedirect.com/science/article/pii/S0167629615001150*

know right now, in what had been the unregulated marketplace prior to the final rule, is that e-cigarettes have emerged as the most popular tobacco product with children and adolescents, with significantly higher use rates than for conventional combustible cigarettes. That is a real and disturbing consequence of these products not being subject to an enforceable federal prohibition against the sale of these products to minors. As regards adult e-cigarette users going forward, FDA expects e-cigarettes and other ENDS to remain on the market for up to three years while seeking marketing authorization. Beyond that time, products that meet the applicable public health standard set forth in the law and receive authorization from FDA can be sold to adult consumers.

Thank you, again, for contacting the FDA. As discussed with your staff on June 9, 2016, we are working on responding to your document request and welcome any follow-up questions. Additionally, if you or your staff would like a briefing on the deeming final rule please let us know.

Sincerely,

Dayle Cristinzio
Acting Associate Commissioner
for Legislation