December 7, 2017

Submitted Electronically
via www.regulations.gov

Food and Drug Administration
Dockets Management Staff (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Dkt. No. FDA-2017-N-5095 for "Existing Center for Tobacco Products Regulatory & Information Collection Requirements"

Dear Sir or Madam:

This letter is sent on behalf of our clients CB Distributors, Inc. ("CB") and DR Distributors LLC ("DR"). CB and DR appreciate the opportunity to provide this comment to FDA regarding the application of Executive Orders 13771 and 13777 ("Executive Orders") to the 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; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 21 CFR Parts 1100, 1140, 1143* ("Deeming Rule").

CB and DR respectfully submit that the current regulatory framework for ENDS products could be far more effective, and far less burdensome if FDA considered ENDS products in a completely different light than traditional combustible tobacco products. In the simplest of terms, regulating a novel non-combustible product in the same scheme as traditional tobacco products is the governmental equivalent of forcing a square peg in a round hole – it just won't work. In light of three recent administrations seeking to streamline regulation in general, FDA has an opportunity in this instance to craft a specific framework for ENDS products based on the novelty of the products, rather than mapping onto ENDS an almost decade-old regulatory framework that was specifically designed for unrelated traditional combustible tobacco products.

Background of Commenters

CB is a distribution company located in Beloit, Wisconsin, and has been in business for over 20 years. CB distributes a wide variety of retail items commonly found in convenience stores across the United States, as well as online. CB and DR import and distribute ENDS components and products. As stakeholders in the ENDS market, CB and DR have expended considerable time and money seeking to stay current and in compliance with requirements under the Deeming Rule. CB and DR believe that by pointing out some of the particular challenges and burdens they have faced, FDA can better partner with serious industry stakeholders to reduce waste and improve compliance consistent with recent Executive Orders.

Presidential Directives

Executive Orders from the Clinton administration, the Obama administration, and most recently, the Trump administration, call for review of regulations with an eye toward evaluating the efficacy and the cost-benefit of existing regulations. Where regulations are ineffective as implemented or where regulations impose significant burdens on the industry and by extension the public, without commensurate benefit, such regulations are prime for review and revision. This policy is echoed in recently proposed legislation, and is reflected in the reinvigoration of the Congressional Review Act.

Inefficiencies of the Deeming Rule

The current application of the Deeming Rule to ENDS products is out of context and inefficient. In the seventeen months since the Deeming Rule went into effect, CB and DR have been challenged by financial burdens and conflicting requirements imposed by the Rule. Not only are the monetary costs burdensome, but compliance is challenging even with the benefit of the Guidance published by FDA to help clarify its expectations. Attempts to contact FDA directly with specific concerns have gone unanswered. While understanding that FDA has challenges of its own relative to the Deeming Rule, clarification of the requirements of the Deeming Rule to ensure it properly reflects the novelty of ENDS products will advance the efficacy of ENDS regulation. This evaluation should begin with the Deeming Rule definitions, which can be a source of considerable difficulty.

- *The Definition of "Tobacco Product" is Too Broad.*

Under the Deeming Rule, the term "tobacco products" encompasses not only products made or derived from tobacco, but also non-tobacco products, non-nicotine products, and component parts such as a ceramic cartomizer, heating coils, vape pen, silicon caps, etc. As a result, the reach of the Deeming Rule extends to products and components that would not ordinarily be included in the realm of "tobacco products."

As it currently stands, manufacturers subject to the Deeming Rule must provide separate submissions (e.g. product listings, ingredient listings, PMTAs, health documents, and reports of HPHCs) for each "tobacco product." Consequently, ENDS manufacturers are forced to devote significant time and resources to provide detailed information about non-tobacco products.

- For each "tobacco product" a manufacturer must submit an ingredient listing. Because of the broad definition of "tobacco product" an ENDS manufacturer must provide a breakdown of substances incorporated into associated devices containing no nicotine or tobacco such as a ceramic cartomizer, e-liquid bottle stoppers, electrode rings, or silicone caps included on a ENDS device. As such, a single "finished tobacco product" ingredient listing can result in an excel workbook full of data breaking down the various "ingredients" of devices, e-liquids, and other items deemed "tobacco products" under the rule.

- Further, each "tobacco product" must bear warning labels on two principal display panels that state the product contains nicotine—or if it does not contain nicotine, the warning must state the product contains tobacco. These warning labels are required even

if the product contained in the packaging does not contain nicotine or tobacco, because the Deeming Rule requires such labels on all "tobacco products", a definition which includes component parts that are sold independent of any tobacco or nicotine containing substance. This requirement results in potentially confusing situations where the actual content of the product may not be accurately reflected on the label.

The broad definition of "tobacco product" has yielded and will continue to yield negative results by placing exponentially higher demands on ENDS manufacturers which are regulated on a per-product basis, and by requiring the placement of potentially confusing warning labels. These issues can be resolved by revising definitions that accurately reflect the products currently on the market.

- *Mapping Traditional Tobacco Product Regulations onto ENDS Products is Not Effective.*

The current context of the Deeming Rule is based on the 2009 regulation of cigarettes and smokeless tobacco, and does not reflect the significant differences between the characteristics of ENDS products. Instead, the Deeming Rule maps the same definitions, standards and requirements for traditional tobacco products onto the ENDS industry. This is impractical for several reasons, and adds substantial burden to certain stakeholders that have no relation to combustible or traditional tobacco products.

When first regulating traditional tobacco products in 2009, FDA allowed certain exemptions for products placed on the market prior to the "grandfather date": February 15, 2007. Seven years later, when extending regulation to ENDS products, FDA adopted the same grandfather date. Unlike traditional tobacco products, the ENDS industry grew and changed significantly between 2009 and 2016, but the current framework failed to keep pace. Given the novelty of ENDS products as a whole, the industry faces unique challenges in identifying a same or substantially equivalent product sold on the United States market on or before February 15, 2007.

Another issue arises from the number of "tobacco products" in the ENDS market compared to traditional tobacco products. In 2014, FDA estimated there were 5,325 cigarette and smokeless tobacco UPCs on the United States market. In contrast, when one considers that a single ENDS manufacturer has separate UPCs for each product based on bottle size, flavor, nicotine content (from 0% to 2.4% and everything in between), single item packaging, multiple-item kits (e-liquid bottle, combination package including e-liquid and cartomizer, combination package including e-liquid, cartomizer, and charger, and so on)—the sheer number of ENDS products far exceeds the number of traditional products. As such, because each individual variation of an ENDS manufacturer's product constitutes a separate "tobacco product," the resulting burden under the Deeming Rule to document each product separately is exponentially increased, results in a disproportionately onerous burden on the ENDS industry.

Regulation Should Reflect Advances in Science and Technology

FDA has recognized that not all of its regulations adequately reflect advances in science, technology or changes in industry practice. Periodic review of the regulatory scheme provides an excellent opportunity to correct the course and develop regulation that adequately reflects scientific and technological advancements. Because of the novel nature of ENDS products,

particularly when compared to centuries old products like cigarettes, ENDS regulation should account for the substantial scientific and technological developments in recent years. As such, revisiting the regulation of ENDS will accomplish the goals of the Executive Orders and will also advance FDA's goal of ensuring its regulations reflect advances in science, technology and changes in industry practice.

Conclusion

Mapping the demands of legacy regulations applicable to traditional tobacco products onto novel ENDS products is expensive, inefficient and ineffective. CB and DR urge FDA to consider new definitions for ENDS products that are better suited to the current state of the industry and the market.

CB and DR greatly appreciate the opportunity to participate in this discussion.

Respectfully,

/s/ Thomas J. Norby

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