December 21, 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-2013-N-0227 for "Tobacco Product Manufacturing Practice; Request for Comments"

Dear Sir or Madam:

This letter is sent on behalf of our clients CB Distributors, Inc. and DR Distributors LLC (collectively "The Companies"). The Companies appreciate the opportunity to provide this comment to FDA regarding the recommended good manufacturing practices for ENDS products in relation to FDA's 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").

The Companies agree with the overall premise of the June 7, 2017 "Proposed Good Manufacturing Practices Regulation to Account for FDA's Deeming Regulation," submitted by RAI Services Company ("Proposed ENDS GMPs") taking the position that ENDS good manufacturing practices ("GMPs") should reflect the nuances of ENDS products. The current regulatory framework for ENDS products would be more effective and less burdensome if FDA regarded ENDS products in a different light than traditional combustible tobacco products given the intrinsic differences between the products. As currently written, the Deeming Rule maps a regulatory scheme specifically designed for traditional combustible products onto an entirely dissimilar product type: ENDS. To address this issue, the Deeming Rule itself and attendant standards, like GMPs, should be revised and clarified to bring practical focus on each class of "tobacco product."

In addition to the Proposed ENDS GMPs provided by certain industry members, there are various ENDS-industry associations that have developed industry standards which could further inform FDA and facilitate the development of ENDS-specific GMPs (e.g. the American E-Liquid Manufacturing Standards Association, and the Global Vapor Standards Association). FDA's engagement with the ENDS industry in this process is greatly appreciated, and The Companies encourage further involvement through meetings with ENDS manufacturers and associations to ensure the GMPs are properly tailored to ENDS products.

Background of Commenters

CB Distributors, Inc. ("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 and online. CB and DR Distributors LLC ("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. The Companies believe that reframing the GMPs applicable to "tobacco products" to reflect the novelty of ENDS products will result in more effective standards, which will still allow for continued innovation and product improvement.

GMPs Must Reflect the Nuances of ENDS Products

To the extent that FDA does not set a bright line distinction between types of "tobacco products", then the best method for setting GMPs is to establish general, base line safety and health controls within which the various "tobacco product" industries can develop specific standards and criteria honed toward their particular product types. Otherwise, as discussed below, many GMP provisions proposed in the January 2012 submission will have no application to a significant part of the industry. The Companies believe that setting general manufacturing standards is the best and most effective way to ensure the GMPs will advance the interest of protecting and promoting public health, while still allowing for continued innovation and product improvement within each industry segment.

The Proposed ENDS GMPs submission highlights some of the distinctions between ENDS and traditional products that demonstrate why separate ENDS GMPs are appropriate, particularly in light of those provisions that are inherently inapplicable to ENDS products:

- Standards relating to agricultural variability in tobacco and tobacco blending standards;
- Commentary that FDA-regulated tobacco products are unsafe or ineffective by virtue of their status as "tobacco products";
- References to inherent risks of traditional tobacco products as identified by Congress and the U.S. Surgeon General; and,
- Standards relating to the processing, handling, or dealing in raw tobacco, given the fact that some ENDS manufacturers may not handle or process tobacco or nicotine-containing products at all.

Because none of these traditional tobacco product oriented factors have any relation to ENDS product manufacture or production, it would be inappropriate to apply such standards to ENDS products. Further, as highlighted in The Companies' December 7, 2017 comment, the ENDS industry has faced challenges stemming from certain definitions within the Deeming Rule, such as the inclusion of non-tobacco products within the concept of "tobacco product." The same challenges arising from overbroad definitions in the Deeming Rule would also extend to compliance with the proposed tobacco GMPs. While the Deeming Rule applies to "tobacco products", "components", and "parts", it does not apply to "accessories." However, it is not clear, in practice, in which category various ENDS elements will fall for the purposes of GMPs.

For example, manufacturers of "accessories" would be excluded from GMP regulations because "accessories" are not covered under the Deeming Rule; however, items that potentially fit within the definition of "accessory" might be considered "components" or "parts" (e.g. "battery cells and control circuitry") that could be subject to GMP regulations. As such, The Companies reiterate their request that FDA revise Deeming Rule definitions to provide more certainty for industry members making efforts to comply with the Deeming Rule requirements and attendant standards, like GMPs.

The Companies encourage FDA to continue to engage and involve the ENDS industry in the rule and standard-making processes, which will further inform FDA's understanding of the ENDS market. The result will be more effective standards and properly tailored GMPs, which will advance the interest in protecting and promoting public health, while still allowing for ENDS product innovation.

The Companies appreciate the opportunity to participate in this discussion.

Respectfully,

/s/ Thomas J. Norby

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