DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

May 6, 2016

Notice to Industry: Additional Tobacco Products Now Regulated by the Food and Drug Administration

Dear Retailer, Manufacturer, Importer, or Distributor:

The U.S. Food and Drug Administration (FDA) recently finalized a 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" (Deeming rule). The Deeming rule will publish in the Federal Register on May 10, 2016, and extends FDA's authority in Chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to additional products that meet the definition of "tobacco product" in the law. This means that while FDA continues to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco products, FDA now also regulates "newly deemed" tobacco products such as electronic cigarettes, cigars, hookah, and pipe tobacco, as well as their components and parts, but not the accessories of newly deemed products. The Deeming rule also includes additional restrictions for "covered tobacco products." A "covered tobacco product" is any newly deemed tobacco product, but excludes any component or part that is not made or derived from tobacco.

Information for Retailers

If a retailer sells a newly deemed tobacco product, then they must comply with the new requirements in the Deeming rule. Retailers must comply with many of these provisions 90 days after publication. Some examples include:

- not selling newly deemed covered tobacco products to anyone under the age of 18;
- requiring age verification by photo ID for anyone under the age of 27 attempting to purchase covered tobacco products;
- not selling covered tobacco products in vending machines (unless in facilities that prohibit persons under the age of 18 from entering at all times); and
- not distributing free samples of newly deemed tobacco products.

In addition, as a result of the Deeming rule, newly deemed tobacco products automatically are required to comply with provisions regarding "tobacco products" found in the FD&C Act and FDA regulations. Among other requirements, all newly-deemed tobacco products will require premarket authorization, unless they are eligible for grandfather status (were on the market as of February 15, 2007 and have remained unchanged since then). FDA does not intend to enforce the premarket authorization requirements for tobacco products that are not grandfathered and are on the market on the effective date of the Deeming rule if manufacturers submit applications for marketing authorization within specific timeframes set forth by FDA. As a result, FDA expects such products currently on the market to remain available for up to three years while manufacturers seek authorization under staggered compliance periods.

The complete requirements for tobacco retailers and the implementation dates for the various provisions that apply to newly deemed products are located on our website.

Information for Manufacturers, Importers, and Distributors

Manufacturers of tobacco products, including newly deemed products, must comply with new requirements as a result of the Deeming rule. Some examples include:

- requiring cigar manufacturers to place specific warning statements on product packaging and advertisements;
- requiring cigar manufacturers and responsible distributors/importers to submit a warning plan to FDA to cover the random display and distribution of warning statements on cigar packaging and quarterly rotation of warning statements in cigar advertisements;
- requiring a nicotine addiction warning statement on product packaging and advertisements of covered tobacco products, cigarette tobacco, and roll-your-own tobacco;
- prohibiting the introduction into interstate commerce of modified risk tobacco products without an FDA order in effect; and
- requiring newly deemed products that are considered "new tobacco products" to be subject to premarket review and authorization.

Manufacturers of newly deemed products must also comply with other requirements, such as, registering their establishments, listing their products with FDA, and submitting lists of ingredients and Harmful and Potentially Harmful Constituents to FDA. At this time, FDA intends to limit enforcement of most of these requirements to finished tobacco products, which means tobacco products, including all components and parts, sealed in final packaging intended for consumer use. The complete requirements for tobacco manufacturers and the implementation dates for the various provisions that apply to newly deemed products are located on our website.

If you believe that your tobacco product should be considered a grandfathered tobacco product and would like an Agency determination on the status of your product, you may submit a grandfather submission for review. CTP issued a guidance document in September 2014, entitled, "Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007," which provides more detail.

It is important to note that Distributors and Importers continue to have responsibilities with respect to tobacco products, including the newly deemed products.

We also note that some retailers (such as some vape shops) may also be considered "tobacco product manufacturers" if they manufacture, fabricate, assemble, label, or process a tobacco product. An establishment that mixes and/or prepares combinations of liquid nicotine, flavors, and/or other liquids, or an establishment that creates or modifies an aerosolizing apparatus for sale to consumers would be considered a tobacco product manufacturer. In that case, the requirements for manufacturers will also apply to the retailer. FDA plans to hold several webinars that will provide more detailed information about these and other new requirements resulting from the Deeming rule.

Resources for Additional Information

FDA has updated its Deeming webpage to include the final rule, information about compliance training webinars for industry, and other information designed to help industry understand the Deeming rule. The Deeming webpage can be found by visiting FDA's website at

www.fda.gov/tobacco and searching for the word "Deeming." FDA will continue to update this page to provide more information to industry and other stakeholders.

We anticipate that many of your questions will be addressed by the resources available on our website (www.fda.gov/tobacco), including the many FDA Tobacco Compliance Webinars we plan to provide and archive on our website. The topics and dates of availability for the tobacco compliance webinars, including one specifically for vape shops, will be posted on our website and updates will be provided as additional webinars are available. In addition, regulated industry may also contact CTP using the following communication methods:

Email:	ASKCTP@fda.hhs.gov
Phone:	1-877-287-1373
Mail:	Food and Drug Administration Center for Tobacco Products 10903 New Hampshire Avenue Silver Spring, MD 20993

Sincerely,

/s/

Ann Simoneau
Director, Office of Compliance and Enforcement
Center for Tobacco Products
U.S. Food and Drug Administration