FDA ALERT

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FDA Issues "Deeming Regulations" Covering Additional Tobacco Products Including Electronic Cigarettes, Cigars and Pipe Tobacco

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On May 10, 2016, the Food and Drug Administration (FDA) issued a final rule (Deeming Regulations) bringing ***cigars, pipe tobacco, electronic nicotine delivery systems (ENDS) (including electronic cigarettes), water pipe (hookah) tobacco, dissolvables and nicotine gels*** (Newly Covered Products) under the agency's tobacco regulatory authority.

The Deeming Regulations subject Newly Covered Products to many of the same regulatory requirements formerly only applicable to cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco, which also includes general controls (such as registration, product listing and ingredient listing), premarket review, sales and marketing restrictions and health warnings.

Notably, the Deeming Regulations –

- Adopt Option 1 from the proposed regulations to include all cigars including *"premium cigars"* under the FDA's tobacco regulatory authority;
- Maintain a "grandfather date" of **February 15, 2007**, for all Newly Covered Products, which means that any Newly Covered Product not commercially marketed in the United States as of **February 15, 2007**; or any modification to a Newly Covered Product where the modified product was not commercially marketed in the United States on or before **February 15, 2007**, will be required to obtain premarket approval before it can be marketed in the United States;
- Do not ban flavored tobacco products. However, the FDA announced that in the future, it intends to propose a product standard prohibiting characterizing flavors in all cigars, including cigarillos and little cigars. Further, the existing tobacco product standard prohibiting characterizing flavors in cigarettes remains in place; and
- Apply the definition of "tobacco product manufacturer" to "vape shops" that mix or prepare e-liquids or create or modify aerosolizing apparatus for direct sale to consumers for use in ENDS, and therefore, subject "vape shops" engaging in these activities to the statutory and regulatory requirements applicable to tobacco product manufacturers.

The following is a summary of the key provisions or application of the Deeming Regulations:

Scope of the Deeming Regulations

The term "tobacco product" is defined by the Federal Food, Drug and Cosmetic Act (FD&C Act) as amended, in part, as ***"any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product."***

The FDA originally only had authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco under the FD&C Act. The Deeming Regulations now bring all other products meeting the definition of "tobacco product," including components and parts, but not accessories of such tobacco products under the regulatory authority of the FDA. Other products satisfying this definition include ***cigars (including***

premium cigars), pipe tobacco, **ENDS (including *e-cigarettes, e-cigars, e-hookah, e-pipes, vape pens, and advanced refillable personal vaporizers), water pipe (hookah) tobacco, dissolvables and nicotine gels***.

Component or Part - Means any software or assembly of materials intended or reasonably expected 1) to alter or affect the tobacco product's performance, composition, constituents, or characteristics; or 2) to be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product.

Examples of components and parts used with ENDS include: e-liquids, atomizers, batteries (with or without variable voltage), cartomizers (atomizer plus replaceable fluid-filled cartridge), digital display/lights to adjust settings, clearomisers, tank systems, flavors, vials that contain e-liquids and programmable software. Examples of components or parts used with water pipe tobacco include: flavor enhancers and the vials in which they are contained, hose cooling attachments, water filtration base additives (including those which are flavored), flavored water pipe tobacco charcoals and the wrappers or boxes that contain the charcoals and bowls, valves, hoses and heads.

General Controls

Registration – Requires owners and operators of domestic companies that manufacture, prepare, compound or process Newly Covered Products to register the name and location of each such establishment. Existing owners and operators are required to register on an annual basis and when adding new establishments. New companies are required to register upon first engaging in the business.

Product Listing – Requires registered companies to file a list of all Newly Covered Products being manufactured, prepared, compounded or processed for commercial distribution. The product list must be filed at the time of registration, and thereafter, on a biannual basis (in June and December), if there are certain changes to the list such as additions or deletions, etc. The product list must be accompanied by certain other information, including a copy of all labeling.

Ingredient Listing – Requires each manufacturer or importer of Newly Covered Products to submit a list of all ingredients, including tobacco, substances, compounds, and additives that are added by the manufacturer to the product by brand and by quantity in each brand or subbrand and to report harmful and potentially harmful constituents (HPHCs) for all Newly Covered Products.

Adulteration & Misbranding – Subjects Newly Covered Products to FDA's adulteration and misbranding enforcement provisions. Adulterated refers generally to degraded or contaminated products, products prepared or packed under insanitary conditions, or products or companies failing to comply with various other regulatory requirements. Misbranded refers generally to products bearing false or misleading package labels, or those being advertised in a false or misleading manner.

Sales & Marketing Restrictions

Ban on Youth Sales – Prohibits retailers from selling Newly Covered Products to anyone younger than 18 years of age and requires age verification of persons 26 years of age and younger.

Ban on Vending Machine Sales – Prohibits retailers from using electronic or mechanical devices, including vending machines, to sell Newly Covered Products, except in locations where no one younger than 18 years of age is present or permitted entry.

Ban on Free Samples – Prohibits the distribution of free samples of Newly Covered Products.

The sales and marketing restrictions will become effective on August 8, 2016.

Premarket Review

The Deeming Regulations require any Newly Covered Product that qualifies as a "new tobacco product" to obtain premarket approval before it can be marketed in the United States. Premarket approval can take any of the following three pathways: 1) submission of a request for an exemption from substantial equivalence (SE) requirements (SE Exemption Request) and receipt of an SE exemption determination; 2) submission of an SE report (SE Report) and receipt of an SE order; or 3) submission of a premarket tobacco product application (PMTA) and receipt of a marketing authorization order.

Grandfather Date / New Tobacco Product – The Deeming Regulations have adopted the existing "grandfather date" of **February 15, 2007**, set forth in the FD&C Act. Therefore, any Newly Covered Product (including those products in test markets) would be considered a "new tobacco product" if it was not commercially marketed in the United States as of **February 15, 2007**; or any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after **February 15, 2007**.

The FDA has reiterated its position that because the "grandfather date" was established by statute, the agency does not believe it has the authority to change the date for Newly Covered Products by regulation. **It should be noted that there is pending legislation before Congress that seeks to amend the "grandfather date" for Newly Covered Products to the effective date of the Deeming Regulations.

Recognizing that many Newly Covered Products were not marketed until after the "grandfather date" and that immediate application of premarket review requirements would cause disruption to the industry, the FDA has established a compliance policy that would delay enforcement of the premarket review requirements. The compliance policy establishes two separate compliance periods, the first, establishes a timeframe for submission and FDA receipt of premarket review applications (the 'initial compliance period") and the second, provides a 12 month timeframe for FDA review of the submissions (the "continued compliance period"). The "initial compliance periods" will be staggered for the three premarket review pathways based on the expected complexity of the applications. Unless the FDA has issued an order denying or refusing to accept a premarket review submission, Newly Covered Products for which timely premarket submissions are made within the "initial compliance period," will be subject to the 12 month "continued compliance period." The FDA does not intend to initiate enforcement for failure to have premarket authorization during the continued compliance period. The compliance periods for the three premarket pathways are as follows:

SE Exemption Requests

Initial	- 12 months from the effective date of the Deeming Regulations
Continued	- 24 months from the effective date of the Deeming Regulations

SE Reports

Initial	- 18 months from the effective date of the Deeming Regulations
Continued	- 30 months from the effective date of the Deeming Regulations

PMTAs

Initial	- 24 months from the effective date of the Deeming Regulations
Continued	- 36 months from the effective date of the Deeming Regulations

Once the "continued compliance period" ends, Newly Covered Products on the market without authorization will be subject to enforcement. However, if at the conclusion of the "continued compliance period," the applicant has provided the needed information and review of the premarket review application has made substantial progress, the FDA may consider on a case-by-case basis whether to defer enforcement for a reasonable time period. Also, any Newly Covered Product that was not on the market on the effective date of the Deeming Regulations (August 8, 2016) is not covered by the above-referenced compliance policy and will be subject to enforcement if marketed without authorization after the effective date.

Modified Risk Claims

The Deeming Regulations prohibit the use of modified risk descriptors (e.g., "light," "low," and "mild") and other modified risk claims related to the Newly Covered Products, unless FDA issues a risk modification order or exposure modification order for the product.

Health Warnings

The Deeming Regulations require the use of the following warning statement on the packages and in the advertisements for all Newly Covered Products and for cigarette tobacco and roll-your-own tobacco: "WARNING: This product contains nicotine. Nicotine is an addictive chemical."

Also, the Deeming Regulations require the use of the following 5 additional warning statements for cigars:

- WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.
- WARNING: Cigar smoking can cause lung cancer and heart disease.
- WARNING: Cigars are not a safe alternative to cigarettes.
- WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.
- WARNING: Cigar use while pregnant can harm you and your baby (Or, as an alternative statement: SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.)

The new rules related to cigars require that all six warning statements (the five immediately above and the addictiveness statement) be randomly displayed and distributed on cigar product packages and rotated in advertisements. The package and advertising warning label requirements must be done in accordance with a warning label plan approved by FDA. In addition, where cigars are sold individually and not packaged, the regulations require that all the cigar warnings be included on a sign at the point-of-sale at each cash register in any retail establishment where the cigars are sold.

The health warning requirements for Newly Covered Products take effect May 10, 2018. However, manufacturers have an additional 30 days after this date, to continue to introduce into interstate commerce existing inventory manufactured before May 10, 2018, that does not contain the required warning statements on packaging. In addition, warning label plans for cigars must be submitted by May 10, 2017.

For further information regarding the Deeming Regulations or the application of the regulations to your business, please contact the following:

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