FDA ALERT

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

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On April 24, 2014, the Food and Drug Administration (FDA) issued its long-awaited proposed regulations (Deeming Regulations) to bring ***electronic cigarettes, cigars, pipe tobacco, water pipe (hookah) tobacco, dissolvables and nicotine gels*** (Newly Covered Products) under the agency's tobacco regulatory authority.

The Deeming Regulations would subject Newly Covered Products to many of the same regulatory requirements currently only applicable to cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco, or a subset of these items. These requirements include general controls (such as registration, product listing and ingredient listing), health warnings, sales and marketing restrictions, and premarket review.

Comments to the proposed regulations must be submitted by **July 9, 2014**.

The following is a summary of the key provisions or application of the proposed 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 currently has authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco and smokeless tobacco under the FD&C Act. The Deeming Regulations seek to bring all other products meeting the definition of "tobacco product," including components and parts, but not accessories of such other tobacco products under the regulatory authority of the FDA. Other products satisfying this definition would include ***electronic cigarettes, cigars, pipe tobacco, water pipe (hookah) tobacco, dissolvables and nicotine gels***.

The Deeming Regulations propose two alternatives regarding the scope of the rule: Option 1 would include all cigars as products covered by the proposed regulations and Option 2 would carve out an exception from coverage for "premium cigars."

A "premium cigar" would be defined as a cigar that: 1) Is wrapped in whole tobacco leaf; 2) contains a 100 percent leaf tobacco binder; 3) contains primarily long filler tobacco; 4) is made by combining manually the wrapper, filler, and binder; 5) has no filter, tip, or non-tobacco mouthpiece and is capped by hand; 6) has a retail price (after any discounts or coupons) of no less than $10 per cigar (adjusted, as necessary, every 2 years effective July 1st, to account for any increases in the price of tobacco products since the last price adjustment); 7) does not have a characterizing flavor other than tobacco; and 8) weighs more than 6 pounds per 1000 units.

General Controls

Registration – Would require 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. Upon publication of the final rules, an initial registration date will be established for existing owners and operators (either December 31, or a later date if publication occurs in the second half of the year).

Product Listing – Would require registered companies to file a list of all Newly Covered Products being manufactured, prepared, compounded or processed for commercial distribution. The product list would 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 – Would require 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 – Would subject 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.

Health Warnings

The Deeming Regulations propose 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 derived from tobacco. Nicotine is an addictive chemical."

Also, the Deeming Regulations propose the adoption of 4 additional warning statements for cigars, including the following:

- Cigar Smoking Can Cause Cancers of the Mouth and Throat, Even If You Do Not Inhale.
- Cigar Smoking Can Cause Lung Cancer and Heart Disease.
- Cigars Are Not a Safe Alternative to Cigarettes.
- Tobacco Smoke Increases the Risk of Lung Cancer and Heart Disease, Even in Nonsmokers.

The proposed rules related to cigars would require the five warning statements (the four above and the addictiveness statement) to be randomly displayed and distributed on cigar product packages and rotated in advertisements. In addition, where cigars are sold individually and not packaged, the proposed rules would require that the cigar warnings all be included on a sign located at the point-of-sale at each cash register in any retail establishment where the cigars are sold.

Sales & Marketing Restrictions

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

Ban on Vending Machine Sales – Would prohibit 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 permitted entry.

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

Modified Risk Claims

The Deeming Regulations would 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.

Premarket Review

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

New Tobacco Product - Significantly, the Deeming Regulations would use the existing "grandfathering" 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**.

FDA has stated that because the "grandfathering" date was set by statute, the agency does not believe it has the authority to change it by regulation.

Recognizing the difficulty that this "grandfathering" date may pose and that many Newly Covered Products may not be "grandfathered," FDA has proposed a compliance policy that would delay enforcement of PMTA and SE requirements for two years. Under this policy, FDA would allow any product marketed between February 15, 2007, and 2 years after the effective date of the regulations, for which the manufacturer submits an SE report by 2 years after the effective date of the regulations, to continue to market its product until such time as the FDA denies the SE submission.

For further information regarding the Deeming Regulations or assistance in preparing comments to the proposed regulations, please contact the following:

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