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The FDA (Food and Drug Administration) Sets its Regulatory Sights on New Tobacco Products in Proposed Rules

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Manufacturers of **electronic cigarettes (e-cigarettes)**, vaporizers, cigars, and other tobacco products could soon be affected by new federal regulations proposed by the U.S. Food and Drug Administration (FDA).

The Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act), which went into effect in 2009, gives FDA the authority to regulate the manufacture, distribution, and marketing of tobacco products. Pursuant to the Tobacco Control Act, FDA currently regulates cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco under a regulatory scheme that requires premarket submissions, restrictions on use of characterizing flavors in cigarettes, requirements on the manner in which cigarettes and smokeless tobacco are sold, as well as other restrictions. The Tobacco Control Act also grants FDA the authority to "deem" other tobacco products to be subject to the restrictions applicable to cigarettes and smokeless tobacco. Industry has long anticipated FDA action on a "deeming regulation."

On April 24, 2014, FDA finally released its long-awaited – and lengthy 241-page – proposed rule extending the agency's authority over these currently unregulated tobacco products. The proposal presents two options for expanding the definition of tobacco products. The first option would impose regulatory controls over all products that meet the definition of a tobacco product. The second option would exempt certain types of cigars from regulation.

Option One – The Sweeping Approach

Under the first, sweeping option proposed by the FDA, all products meeting the definition of a tobacco product, including e-cigarettes, all types of cigars, pipe tobacco, nicotine gels, waterpipe (or hookah) tobacco, and dissolvable tobacco products, would be subject to regulatory controls similar to cigarettes and smokeless tobacco. Under the proposal, FDA would also reserve the right to regulate future tobacco product categories that have not been invented yet. Only certain accessories of a proposed deemed tobacco product would be exempt from the regulatory requirements.

These newly-deemed tobacco products would be subject to the following provisions from the

Tobacco Control Act:

- Required submission of ingredient listing and reporting of potentially harmful constituents;
- Required registration and product listing;
- Prohibition against advertising statements regarding a reduction in risk (such as the descriptors “light,” “low,” and “mild”) compared to other tobacco products without FDA approval;
- Prohibition against distributing free product samples; and
- Mandated FDA review and approval of tobacco products before marketing.

In addition to these requirements which are already in place for tobacco products, the FDA’s proposed rules suggest incorporation of certain new provisions:

- Prohibition against sales to minors;
- Prohibition of vending machine sales unless the vending machine is not accessible to minors; and
- Addition of health warnings for product packages and advertisements.

While a restriction on the use of characterizing flavors in these other tobacco products is not expressly included, FDA has requested “comments on the characteristics or other factors it should consider in determining whether a particular tobacco product is a ‘cigarette’ . . . and . . . subject to the prohibition against characterizing flavors, despite being labeled as a little cigar or other non-cigarette tobacco product.” FDA is also seeking “research regarding the long-term effects of flavored tobacco product usage including data as to the likelihood of whether users of flavored tobacco products initiate cigarette usage and/or become dual users with cigarettes.”

Option Two – Deeming Certain Cigars

The second, more limited option presented by the FDA would deem only a subset of cigars as subject to the regulatory controls established in the first option, which are defined as “covered cigars.” Under the proposed rule, covered cigars would exclude any cigar that meets the following eight (8) criteria:

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;

7. Does not have a characterizing flavor other than tobacco; and

8. Weighs more than 6 pounds per 1000 units.

Cigars meeting these criteria are referred to as “premium cigars” in the proposed rule. FDA also requests comments on whether a production rate or volume restriction should be included as criteria for premium cigars.

Notwithstanding the possibility of including a ninth criterion, the requirements for premium cigars are overly proscriptive. For example, the limitation on weight may potentially exclude cigars on the lower end of length and ring gauge. Further, some expensive cigars use characterizing flavors, despite otherwise being marketed as a premium cigar. FDA may be better served with one or more mandatory criteria (such as a minimum retail price), along with meeting a specific number of additional criteria (such as no characterizing flavors or weight).

Issues Regarding Premarket Approval

Although FDA did not propose an outright ban on advertising, Internet-based sales, or the use of flavorings in products, there are significant problems with the proposed rule for newer tobacco products such as electronic cigarettes. As part of the deeming regulation, FDA proposes to require all tobacco products not commercially marketed in the United States as of February 15, 2007 to require an approved premarket application.

FDA proposes to grant a 24-month period following the date the final rule is issued, where manufacturers may submit marketing applications. Provided such applications are submitted, FDA will exercise enforcement discretion on the continued marketing of those tobacco products. Despite this, many newer types of tobacco products, including electronic cigarettes, will require more detailed premarket applications under section 910(c)(1)(A)(i) of the Federal Food, Drug and Cosmetic Act, as opposed to the less detailed substantial equivalence applications under section 910(a)(2)(A) of the Act. This is because many, if not all, electronic cigarettes, were marketed after February 15, 2007.

According to FDA, “[w]e do not believe that we have the authority to alter or amend this grandfathering date, which is set by statute.” Notwithstanding this interpretation, FDA has the option to exercise enforcement discretion over products marketed prior to enactment of the deeming regulation.

FDA Seeking Public Input

The proposed rules are open to public comment for seventy-five days from the date of their release before the FDA makes final changes. One question specifically posed by the FDA, and on which it is seeking input, is whether all cigars should be subject to deeming rather than the proposed carve-out for premium cigars. The FDA is also seeking input on how to implement the restrictions with respect to e-cigarettes, and has asked for health and behavioral data about the effects of using e-cigarettes. Although e-cigarettes do not contain tobacco per se, the FDA has maintained that it can regulate e-cigarettes under the Tobacco Control Act because they contain nicotine derived from tobacco. Given that health experts have not said much about the known effects, if any, of e-cigarettes, the agency is seeking additional information about these products.

Although the proposed rule will not be finalized for some time, and will include a 24-month period for manufacturers to submit product applications, companies should begin preparations now. Based on FDA's interpretation of the Tobacco Control Act, most requirements have been set by Congress and may not be modified by FDA's regulations. This means that product applications will be required for any product covered by FDA's deeming regulation. Companies should begin preparations by collecting documentation that products were marketed prior to February 15, 2007, if possible. Companies should also consider what information will be necessary for their marketing applications.

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