

FDA to Regulate E-Cigarettes, Cigars and Other Tobacco Products

Manufacturers and retailers must receive premarket authorization for newly deemed tobacco products and comply with other requirements related to FDA's long-anticipated deeming rule.

On May 10, 2016, the U.S. Food and Drug Administration (FDA) published the long-anticipated final "deeming rule," which extended the FDA's tobacco product authorities under the federal Food, Drug, and Cosmetic Act (FDCA) to all products meeting the statutory definition of "tobacco product," including, among others, e-cigarettes, gels, e-vapor, dissolvables, pipe tobacco, hookah tobacco, cigars, and novel and future tobacco products.¹ Simultaneously, FDA announced the availability of several guidance documents related to premarket tobacco product applications for electronic nicotine delivery systems,² tobacco product master files³ and the deeming regulation,⁴ as well as a user fee rule⁵ (and accompanying small entity compliance guide⁶) for domestic manufacturers and importers of cigars and pipe tobacco. The flurry of regulatory activity is the latest and most significant step in FDA's evolving authority over the tobacco industry and several novel "tobacco" products which, to date, have escaped FDA oversight.

Overview of the Deeming Rule

The FDCA, as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), authorized FDA to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and any other tobacco products that the Agency by regulation deems to be subject to the law. Under this authority, FDA first released its proposed deeming regulation on April 25, 2014, which floated the possibility of excluding so-called "premium cigars" from the final rule.⁷ Ultimately, no exemption for "premium cigars" was included in the final rule as FDA determined that all cigars pose serious negative health risks, youth and young adults use premium cigars, and the available evidence provides no basis for FDA to conclude that the patterns of premium cigar use sufficiently reduce the health risks to warrant exclusion.⁸

Under the deeming rule, all products that meet the statutory definition of "tobacco product"⁹ in the FDCA are subject to FDA's authority to regulate tobacco products, except for accessories of newly deemed tobacco products. Notably, components and parts of newly deemed tobacco products are subject to FDA's tobacco product authorities, but the accessories of newly deemed tobacco products are not. To illustrate, e-liquids, tank systems and vials that contain e-liquids are components and parts (and subject to regulation as tobacco products), while screwdrivers and lanyards are accessories exempt from regulation as tobacco products.

Product Category	Components and Parts	Accessories
Table 1: Examples of Distinction Between Components and Parts and Accessories		
Electronic Nicotine Delivery Systems (ENDS) (including e-cigarettes) ¹⁰	E-liquids; atomizers; batteries; cartomizers (atomizer plus replaceable fluid-filled cartridge); digital display/lights to adjust settings; clearomisers; tank systems; flavors; vials that contain e-liquids; programmable software; coils; wires; screws; silica.	Screwdrivers and lanyards.
Waterpipe Tobacco ¹¹	Pipes; flavor enhancers and the vials in which they are contained; hose cooling attachments; water filtration base additives (including those which are flavored); flavored hookah charcoals and the wrappers or boxes that contain the charcoals; bowls; valves; hoses; and heads.	Hookah glow balls; foil pokers; shisha oyster forks; tongs; and bags.

Once the regulation is effective, deemed products will be subject to the same FDCA provisions that govern currently regulated products (e.g., cigarettes), such as the prohibitions against adulteration or misbranding tobacco products, as well as the prohibition on unauthorized use of modified risk descriptors (e.g., “light,” “low” and “mild” descriptors) and claims. The final rule also subjects deemed products to FDA’s requirements governing ingredient and product listing, reporting harmful and potentially harmful constituents (HPHCs), establishment registration, premarket review and compliance with any applicable tobacco product standard.

In addition to the FDCA provisions that apply automatically to the deemed products, FDA also has authority to place “restrictions on the sale and distribution of a tobacco product” if FDA determines the restrictions are appropriate for the protection of the public health. Thus, the final deeming rule subjects the deemed products to additional sale and distribution requirements, including minimum purchase age and identification; mandatory display of health warning statements on product packages and advertisements; prohibitions on vending machine sales (except in adults-only facilities); and distribution of free samples. According to FDA, these additional restrictions are necessary in light of the impact of nicotine on youth and young adults; the health risks of the deemed products; consumer confusion; and misinformation about certain deemed products.

Premarket Review and Authorization Requirements

Deemed products are subject to the same premarket review provisions of Sections 905(j) and 910 of the FDCA that govern currently regulated tobacco products, meaning that manufacturers of newly deemed products will be required to obtain premarket authorization through one of three premarket pathways: SE Exemption Requests; SE Reports; or Premarket Tobacco Product Applications (PTMAs). In the final rule, FDA reiterated its previously articulated position that FDA lacks authority to change the “grandfather date” from February 15, 2007, as the date is specified by statute. Because most e-cigarette and vapor products were commercially marketed after the grandfather date, the deeming rule effectively mandates that these products will be subject to the PMTA review process. That said, in the final rule, FDA identified “a non-flavored e-cigarette (also marketed as an ‘e-cigar’) that may have been on the market on February 15,

2007,” and observed that “this product may possibly be able to serve as an appropriate predicate for purposes of the SE pathway.”¹²

Under the deeming rule, manufacturers of all newly deemed tobacco products will have a 12, 18 or 24-month initial compliance period in which to prepare applications for marketing authorization, as well as a 12-month continued compliance period after those dates in which to obtain FDA authorization (resulting in a total compliance period of 24, 30 or 36 months during which FDA does not intend to take enforcement action for failing to have premarket authorization). After the continued compliance period ends, new tobacco products on the market without authorization will be subject to FDA enforcement. Importantly, the aforementioned compliance policy applies only to products that are commercially marketed as of the effective date of the deeming rule (*i.e.*, August 8, 2016): any new tobacco product not on the market as of the effective date is not covered by the compliance policy and is subject to enforcement if marketed without premarket authorization.¹³

Premarket authorization	Initial compliance period for manufacturers to submit (and FDA to receive) premarket filing	Continued compliance period for receipt of premarket authorization	Total compliance period
Table 2: Compliance Period for Newly Deemed Tobacco Products (Marketed as of Aug. 8, 2016)			
SE Exemption Requests	12 months (Aug. 8, 2017)	12 months (Aug. 8, 2017)	24 months (Aug. 8, 2018)
SE Reports	18 months (Feb. 8, 2018)	12 months (Aug. 8, 2017)	30 months (Feb. 8, 2019)
PMTAs	24 months (Aug. 8, 2018)	12 months (Aug. 8, 2017)	36 months (Aug. 8, 2019)

Tobacco Retailers

Certain aspects of the deeming regulation will be of particular interest to retailers. For example, the deeming regulation renders all cigarettes, smokeless tobacco and covered tobacco products in a retailer’s establishment subject to the same age and identification requirements (18 years, as verified by photo ID, but there is no requirement to verify the age of a person older than 26 years). In addition, the final rule prohibits vending machine sales of newly deemed products, unless the vending machine is located in a facility where the retailer ensures that individuals under 18 years of age are prohibited from entering at any time. Finally, the deeming regulation includes retailer exceptions limiting liability for the sale or distribution of non-compliant packaging that (i) contains a health warning; (ii) the manufacturer, importer or distributor supplied to the retailer; and (iii) the retailer has not altered in a material way.¹⁴

Vape Shops Acting as Manufacturers

Under the final rule, establishments that mix or prepare e-liquids or create or modify aerosolizing apparatuses for direct sale to consumers for use in electronic nicotine delivery system (ENDS) products are tobacco product manufacturers under the FDCA and, accordingly, are subject to the same legal requirements that apply to other tobacco product manufacturers.¹⁵ As such, under the rule, the tobacco products that vape shops mix and/or prepare are new tobacco products within the meaning of section

910(a)(1) of the FDCA. Vape shops acting as manufacturers are therefore required to obtain premarket authorization for each non-grandfathered product (*i.e.*, e-liquid) they prepare for sale or distribution to consumers, subject to the compliance policy outlined above.

Flavored Products

Flavored tobacco products are subject to the premarket authorization requirements applicable to other deemed tobacco products. In the final rule, FDA expressed concern that some tobacco products, such as e-cigarettes and cigars, are being marketed with characterizing flavors, and that these flavors can be especially attractive to youth, potentially placing youth at risk of tobacco-related disease and death. However, the final rule also acknowledged the “emerging evidence that some adults may potentially use certain flavored tobacco products to transition away from combusted tobacco use.”¹⁶ Although the deeming regulation does not ban flavored tobacco products, the final rule does announce that FDA intends to issue a proposed product standard that would “eliminate characterizing flavors in all cigars including cigarillos and little cigars.”¹⁷

Small-Scale Tobacco Product Manufacturers

Under the final rule, “small-scale tobacco product manufacturers” — manufacturers of any regulated tobacco product that employ 150 or fewer full-time equivalent employees with annual total revenues of US\$5 million or less — are provided with additional time to comply with certain provisions of the rule (*i.e.*, additional time to respond to SE deficiency letters, an additional six-month compliance period for the tobacco health document submission requirements and additional time to submit ingredient listings).¹⁸

Implications of the Deeming Rule

As a practical matter, manufacturers of newly deemed tobacco products will likely scramble to market new tobacco products in advance of August 8, 2016 — the effective date of the deeming regulation — to ensure that they receive the benefit of FDA’s premarket authorization compliance policy. Even so, absent legislation moving the grandfather date, the deeming rule will impose severe burdens on manufacturers and retailers of ENDS products. Indeed, the final rule acknowledges that imposing the regulatory regime “inevitably will lead to some market change and consolidation.”¹⁹ In light of the pending regulatory changes, it is incumbent on industry to consider the implications of the new requirements and the means to ensure compliance with evolving FDA regulation.

If you have questions about this *Client Alert*, please contact one of the authors listed below or the Latham lawyer with whom you normally consult:

John R. Manthei

john.manthei@lw.com
+1.202.637.2211
Washington, D.C.

J. Benneville (Ben) Haas

ben.haas@lw.com
+1.202.637.1084
Washington, D.C.

Adam M. Susser

adam.susser@lw.com
+1.202.537.2239
Washington, D.C.

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Endnotes

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- ¹ 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; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28974 (to be codified in 21 CFR Part 1100, 1140, and 1143) [Deeming Rule].
 - ² FDA, Draft Guidance for Industry: Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (May 2016), *available at*, <http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM499352.pdf>.
 - ³ FDA, Guidance for Industry: Tobacco Product Master Files (May 2016), *available at*, <http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM499350.pdf>.
 - ⁴ FDA, Small Entity Compliance Guide: FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirement's for Packages and Advertisements (May 2016), *available at*, <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm499355.htm>.
 - ⁵ Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Cigars and Pipe Tobacco, 81 Fed. Reg. 28707 (May 10, 2016) (to be codified at 21 CFR Part 1150).
 - ⁶ FDA, Small Entity Compliance Guide: Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products (May 2016), *available at*, <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm499355.htm>.

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- ⁷ 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, 79 Fed. Reg. 23142 (proposed Apr. 25, 2014) (to be codified in 21 CFR Part 1100, 1140, and 1143).
- ⁸ Deeming Rule, 81 Fed. Reg. 28974, 29020 (May 10, 2016).
- ⁹ 21 U.S.C. § 321(rr)(1).
- ¹⁰ Deeming Rule, 81 Fed. Reg. 28974, 29016 (May 10, 2016).
- ¹¹ *Id.*
- ¹² *Id.*, at 28991.
- ¹³ FDA, Small Entity Compliance Guide: FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirement's for Packages and Advertisements (May 2016), at 17, *available at*, <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm499355.htm>.
- ¹⁴ Deeming Rule, 81 Fed. Reg. 28974, 29060 (May 10, 2016).
- ¹⁵ *Id.*, at 28979.
- ¹⁶ *Id.*, at 28977.
- ¹⁷ *Id.*, at 29024.
- ¹⁸ *Id.*, at 29026.
- ¹⁹ *Id.*, at 29044.