The Deeming Regulation: FDA Authority Over E-Cigarettes, Cigars, and Other Tobacco Products

On May 10, 2016, the U.S. Food & Drug Administration (FDA) took an important step to protect public health by publishing a final regulation to begin regulating e-cigarettes, cigars, pipe tobacco, and hookah. The Family Smoking Prevention Tobacco Control Act of 2009 granted the FDA the authority to regulate all tobacco products,[1] but only required the FDA to regulate cigarettes, cigarette tobacco, smokeless tobacco, and roll your own tobacco.[2] To regulate all other products, the agency was required to issue a rule that "deems" those products to be within the FDA's authority.

Nearly seven years after Congress authorized action, the FDA has issued its final deeming regulation that brings all tobacco products under its authority. The final deeming regulation is an important foundation for protecting public health and includes many improvements over the initial proposal. This factsheet explains what this new rule means for federal tobacco regulation and what steps the FDA must still take to protect public health.

Given the limits on FDA authority as well as the slow pace of the federal regulatory process, state and local governments retain their critical role of implementing bold, evidence-based tobacco control policies to protect health in their communities. FDA regulation will complement – not replace – local action. For more information on what state and local governments can do in light of the deeming regulation, see State and Local Tobacco Regulation in a Post-Deeming World.

What products does the FDA now regulate?

The deeming regulation allows the FDA to regulate any product that is "made or derived from tobacco that is intended for human consumption." [3] This includes cigars, e-cigarettes, hookah, pipe tobacco, dissolvable tobacco products, and any other product containing tobacco, or nicotine derived from tobacco. The regulation also deems any future tobacco products that meet the statutory definition of "tobacco product" under the Act to be within the FDA's authority. This ensures that new and emerging tobacco products will be subject to all of the requirements and restrictions in place without having to go through an additional deeming rulemaking process.

Unfortunately, the Tobacco Control Act prohibits the FDA's Center for Tobacco Products (CTP) from regulating products that do not contain either tobacco or nicotine. Some e-cigarette liquid is labeled nicotine-free, and may therefore be beyond the reach of CTP.[4] However, any liquid that

does contain nicotine, when it claims not to, is a tobacco product subject to FDA enforcement action as a "misbranded tobacco product."

How does the FDA regulate tobacco product parts and accessories?

The Tobacco Control Act definition of tobacco products includes any component, part, or accessory of such products. However, the deeming regulation specifically excludes from FDA regulation any "accessories" of the newly-covered products. Components and parts (terms that are used interchangeably by the agency) of the newly-covered tobacco products will be regulated, but their related accessories will not. The FDA's decision to exclude all newly-covered products' accessories could create federal regulatory gaps for new and emerging products like e-cigarettes. The FDA has also excluded "any component or part that does not contain tobacco or nicotine" from some of the new restrictions. For example, the regulation does not impose a federal minimum sales age requirement for electronic cigarette devices that are sold without liquid or with liquid that is free of nicotine.

Does the FDA restrict or prohibit advertising of e-cigarettes?

While the advertising of cigarettes and smokeless tobacco on television and radio was prohibited in 1971[5] and 1986[6] respectively, there are no restrictions on the advertising of e-cigarettes. The FDA has broad authority to restrict the advertising and marketing of all tobacco products.[7] However, the deeming regulation does not limit the advertising and marketing of e-cigarettes or other newly-covered tobacco products, except that these products are now subject to FDA action for false or misleading and unauthorized modified risk claims. The FDA retains the authority to restrict advertising and marketing in the future but has not done so at this time.

Are flavored tobacco products prohibited?

The Tobacco Control Act prohibits characterizing flavors in cigarettes, with the exception of menthol and tobacco, but the FDA has not extended that provision to any other products. All other tobacco products, including e-cigarettes and little cigars, known for their use of youth-attractive flavors, can continue to be sold with any fruit, candy, or menthol flavor unless state or local sales restrictions are in place.

In the materials accompanying the deeming regulation, the FDA expressed its intention to propose a tobacco product standard that will prohibit characterizing flavors – except menthol – for all cigars in the future. While it is important to get fruit- or candy-flavored cigars off the market, a tobacco product standard to prohibit all flavors in all products could do more to protect health. A regulation that prohibited all characterizing flavors – including menthol – in all tobacco products, would go much further to reduce tobacco use among youth, women, African Americans, the LGBT community, and other disproportionately affected populations.

Are newly-covered products subject to premarket review by the FDA?

Premarket review will be mandatory; however, the FDA will delay the enforcement of this requirement until 12, 18 or 24 months after the rule takes effect on August 8, 2016, depending on the kind of application. During the applicable time period, manufacturers are free to market new products so long as they submit an application to the FDA. After that time period ends, manufacturers can continue to market products that have already been introduced for an additional 12 months or until the FDA acts on the application. Any products that do not have a marketing authorization by the end of this second compliance period can be removed from the market by the FDA. An analogous process was established during the passage of the Act that applied to cigarettes and smokeless tobacco products. This process did not have a final deadline for the removal of products that the agency did not act on. For the original process, the FDA received 3,517 applications but five years later has only issued orders removing 27 products from the market. After the withdrawal of 383 applications and the authorization of 98 applications, the tobacco companies are still able to market the unauthorized products represented by the 3,009 outstanding applications. The deeming regulation's establishment of a final deadline is an improvement, provided that the FDA's guiding principal in exercising its enforcement discretion is protecting public health. See the Consortium's webpage, Tobacco Product Applications, for more information on the FDA's authority and actions related to premarket review.

When will the deeming regulation take effect?

The FDA began enforcing some of the new requirements on August 8, 2016, ninety days after the May 10 publication date. However, the agency is delaying the enforcement of many provisions much further into the future, as noted in Table 1, below. While the deeming regulation has been challenged in court, so far no court has delayed the implementation of the FDA's regulations. For information on pending litigation, see Lawsuits Challenging the FDA's Deeming Rule.

What other restrictions apply to each product?

While the FDA has broad regulatory authority over newly-covered products, there are many restrictions that currently apply to cigarettes and smokeless tobacco that the FDA did not extend to newly-covered products. Table 2 lists some of the policies that will, and will not, apply to newly-covered products.

Table 1
Timeline for FDA Enforcement for Newly-covered Tobacco Products

FDA Policy	Enforcement Date
Minimum sales age of 18 and age verification under 27	August 8, 2016
Prohibition on vending machine sales except adults-only facilities	August 8, 2016
Prohibition on free samples[8]	August 8, 2016
Regulation of adulterated products	August 8, 2016
Prohibition on false or misleading advertising	August 8, 2016
Required premarket review of modified risk tobacco products	August 8, 2016
Required disclosure of health-related documents	February 8, 2017
Required registration of manufacturers and disclosure of product lists	September 30, 2017
Required disclosure of ingredients, substances, compounds and additives	November 8, 2017
Applications for premarket review of tobacco products seeking a substantial equivalence exemption marketing order	November 8, 2017[9]
Prohibition of the use of "light," "mild," "low," or similar descriptors	November 8, 2017 + 30 day sell-off period
Required premarket review of tobacco products seeking a substantial equivalence marketing order	May 8, 2018[10]
Required warning labels	August 10, 2018
Required premarket review of tobacco products seeking a PMTA marketing order	November 8, 2018[11]
Required disclosure of harmful and potentially harmful constituents	November 8, 2019

All of these requirements currently apply to cigarettes, cigarette tobacco, smokeless tobacco and roll-your-own tobacco.

Table 2
Final Deeming Regulation Provisions

				
Minimum sales age of 18 and age verification under 27	✓	✓	✓	✓
Prohibition on vending machine sales	Allowed in adults-only facilities	Allowed in adults-only facilities	Allowed in adults-only facilities	Allowed in adults-only facilities
Prohibition on self-service displays	Allowed in adults-only facilities	Allowed in adults-only facilities		
Minimum package size requirements	✓			
Prohibition on breaking packages by retailers (e.g., sales of loosies)	✓	✓		
Prohibition on free samples[12]	✓	Allowed in qualified adults-only facilities	✓	✓
Prohibition on characterizing flavors	Menthol and tobacco allowed			
Mandatory warning labels on packages and advertisements	9 Rotating warnings	4 Rotating warnings	6 Rotating warnings[13]	1 Static warning
Prohibition on brand names on non-tobacco products and brand name sponsorship of sporting and cultural events	✓	✓		
Required notice of advertising in any non-traditional medium	✓	✓		

Other Resources

For more information on the FDA's regulation of tobacco products, visit our FDA Tobacco Action Center.

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[1] Family Smoking Prevention and Tobacco Control Act § 101(a), Pub. L. No. 111-31, 123 Stat. 1783 (2009) (codified at 21 U.S.C. § 321(rr)(1)) [hereinafter Tobacco Control Act].

[2] Tobacco Control Act, § 901(b), 123 Stat. at 1786 (codified at 21 U.S.C. § 387a(b)).

[3] Tobacco Control Act, § 101(a), 123 Stat. at 1783 (codified at 21 U.S.C. § 321(rr)(1)).

[4] The FDA has indicated that even products that do not contain tobacco or nicotine may still be regulated if they are components or parts of tobacco products. 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; Final Rule, 81 Fed. Reg. 28,974, 29,032 (May 10, 2016) (to be codified at 21 C.F.R. pts. 1100, 1140, and 1143)).

[5] 15 U.S.C. § 1335.

[6] 15 U.S.C. § 4402(c).

[7] Tobacco Control Act, § 906(d), 123 Stat. at 1796 (codified at 21 U.S.C. § 387f(d)).

[8] The FDA has stated that "allowing prospective adult buyers to smell or handle one of the newly deemed products is not considered distribution of a 'free sample' as long as the free product is not actually consumed, in whole or in part, in the retail facility and the prospective buyer does not leave the facility with a free tobacco product." 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; Final Rule, 81 Fed. Reg. 28,974, 29,026 (May 10, 2016) (to be codified at 21 C.F.R. pts. 1100, 1140, and 1143)).

[9] Products for which an applications has been filed by this date may remain on the market for up to 12 months until the FDA makes a decision whether to issue a marketing order.

[10] Id.

[11] Id.

[12] The FDA has stated that "allowing prospective adult buyers to smell or handle one of the newly deemed products is not considered distribution of a 'free sample' as long as the free product is not actually consumed, in whole or in part, in the retail facility and the prospective buyer does not leave the facility with a free tobacco product." 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; Final Rule, 81 Fed. Reg. 28,974, 29,026 (May 10, 2016) (to be codified at 21 C.F.R. pts. 1100, 1140, and 1143)).

[13] In the proposed deeming rule, FDA proposed to require four of the five warnings already included on most cigar packages and in most cigar advertisements as a result of settlement agreements between the Federal Trade Commission (FTC) and the seven largest U.S. cigar manufacturers. The final deeming regulation requires a fifth warning regarding reproductive health effects and cigar use specifically, which reads "WARNING: Cigar use while

pregnant can harm you and your baby." The FDA notes in the final rule materials that this requirement is supported by existing scientific evidence and is appropriate for the protection of the public health. However, because the general statement "Tobacco smoke increases the risk of infertility, stillbirth and low birth weight" is also a true statement, and because scientific evidence demonstrates that cigar smoke is similar in content and effects to cigarette smoke, the FDA will allow the use of the reproductive health warning required by the FTC settlement agreement as an optional alternative to the fifth FDA warning. In addition, cigarette tobacco, roll-your-own tobacco, and the newly covered tobacco products will have a required warning label regarding addictiveness.