

# FDA Issues Advanced Notice of Proposed Rulemakings Regarding Premium Cigars and Tobacco Product Flavors



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In FDA's latest effort to implement its comprehensive plan for tobacco and nicotine regulation, the Agency published two additional advanced notice of proposed rulemakings (ANPRMs) concerning regulation of premium cigars and tobacco product flavors. Specifically, on March 21, 2018, the FDA published an ANPRM, "Regulation of Flavors in Tobacco Products," which solicited comments on, among things, the role of flavors (other than tobacco) (hereinafter, "flavors") on initiation and patterns of tobacco product use and on transitioning combustible to non-combustible tobacco product use.<sup>[1]</sup> The next week, on March 26, 2018, the FDA published another ANPRM, "Regulation of Premium Cigars," which requested input on the definition and use patterns of premium cigars as well as public health considerations associated with premium cigars.<sup>[2]</sup> While these regulatory actions were initially promised in FDA's July 28, 2017 comprehensive plan for tobacco and nicotine regulation, publication of the ANPRMs in the *Federal Register* provide an indication of the Agency's regulatory priorities going forward.<sup>[3]</sup>

## Flavored Tobacco Products ANPRM

In the ANPRM regarding regulation of tobacco product flavors, FDA requests

comments on, among other topics, the following:

- *The Role of Flavors (other than tobacco) in Tobacco Products*: FDA requested studies or information regarding the role of flavors generally in tobacco products, as well as the appropriateness of extrapolating research from other areas (e.g., consumer products) to the tobacco space.<sup>[4]</sup>
- *Flavors (other than tobacco) and Initiation and Patterns of Tobacco Product Use, Particularly Among Youth and Young Adults*: FDA requested studies or information regarding the role of flavors in: (1) initiation and/or patterns of use of combusted and non-combusted tobacco products among youth and young adults; (2) in non-combusted tobacco products on initiation of tobacco product use or progression to use of other tobacco products among youth and young adults.<sup>[5]</sup>
- *Flavors (other than tobacco) and cessation, dual use, and relapse among current and former tobacco product users*: FDA requested information on the role of flavors in helping adult cigarette smokers reduce cigarette use and/or switch to potentially less harmful tobacco products. Further, FDA requested studies or information concerning the role of flavors in non-combusted tobacco products on the likelihood of: (i) cessation of combusted tobacco product use; (ii) cessation of all tobacco product use; and (iii) uptake of dual use of combusted and non-combusted tobacco products among current and former tobacco product users.”<sup>[6]</sup> FDA also requested information on the role of flavors in combusted products on the likelihood of: (1) delayed or impeded cessation among users who would have otherwise quit combusted tobacco product use; or (2) delayed or impeded cessation among users who would have otherwise quit all tobacco product use. FDA also solicited studies or information regarding the role of flavors in non-combusted tobacco on the likelihood that former combusted tobacco product users relapse.<sup>[7]</sup>
- *Additional Public Health Considerations*: FDA requested studies or information regarding (1) the potential toxicity or adverse health effects to the user or others from any flavors (e.g., flavor additives, compounds or ingredients) in tobacco products; (2) the impact of public health efforts by local jurisdictions, States, and members of the international community to impose restrictions on the manufacture, marketing, sale or distribution of all or a subset of tobacco products with flavors, including but not limited to, cigars, ENDS, menthol cigarettes, and smokeless tobacco products; (3) consumer perceptions of the health risk of tobacco products with flavors when compared to other tobacco products both with and without flavors; (4) consumer perceptions, if any, of the addictiveness of tobacco products with flavors.

In a contemporaneous statement accompanying the ANPRM, FDA Commissioner Scott Gottlieb, M.D called upon all stakeholders to “share data, research, and information that can inform our process for examining the role that flavors – including menthol – play in initiation, use and cessation of tobacco products.<sup>[1]</sup> Importantly, the FDA Commissioner also requested “personal stories” from individuals that have been aided by flavors in making the transition between combustible tobacco cigarettes and vaping. As seen in the litigation surrounding the deeming rule, these regulatory comments could be cited in any future litigation regarding either of these issues.

Comments are due on the tobacco product flavors ANPRM by June 19, 2018.

## **Premium Cigars ANPRM**

In the preamble to the ANPRM regarding premium cigars, FDA noted that it received “numerous comments on the deeming proposed rule with respect to premium cigars, both in favor of, and against, regulating these products.”<sup>[8]</sup> However, FDA explains that there was a lack of data supporting the opinions expressed in the comments received by the Agency regarding the Deeming Rule. For that reason, the ANPRM explains that “FDA is seeking comments, evidence, information, data, and analysis that were not submitted in response to the proposed deeming rule” that could inform FDA’s thinking with respect to regulation of premium cigars.<sup>[9]</sup>

As an example of the type of information that would be responsive to the ANPRM, FDA cites a PATH Study Paper, which analyzed findings from the 2013-2014 Population Assessment of Tobacco and Health (PATH) Study with a focus on smokers of filtered cigars, cigarillos, and traditional cigars, which were further classified by study authors as either “premium” or “nonpremium.”<sup>[10]</sup> That study concluded that “use characteristics, cigar smoking patterns, and dual smoking with cigarettes varied by cigar type.”<sup>[11]</sup>

Specifically, in the ANPRM, FDA requests comments on, among other topics, the following:

- *Definition of Premium Cigars:* Among other things, FDA requested comments from the public concerning the defining characteristics of premium cigars, which may include: size; tobacco filler type; fermentation type; wrapper and binder composition; where the tobacco used for premium cigar filler or wrappers is grown; presence or absence of a filter or mouthpiece; manufacturing and assembly process; rate of production; presence or absence of flavor imparting compounds, flavor additives, or characterizing flavors other than tobacco; presence or absence of any additives other than cigar glue; nicotine content; tar and carbon monoxide delivery amounts; retail price; frequency with which price changes; packaging quantity and size; any action directed to consumers by a retailer or manufacturer.<sup>[12]</sup>
- *Use Patterns of Premium Cigars:* FDA solicited studies or information regarding, among other things, and as compared to other cigars: (1) the potential role of premium cigars on tobacco initiation and progression to use of other tobacco products; (2) behavioral data related to dual use of premium cigars and other tobacco products; (3) the frequency and intensity of premium cigar use; (4) the proportion of premium cigar smokers showing symptoms of dependence; (5) the abuse liability of premium cigars; (6) the impact of premium cigar labeling, advertising, and marketing efforts on patterns of use. Lastly, FDA also requested information on the extent to which users of other tobacco products might switch to premium cigars if FDA were to exempt premium cigars from regulation or regulate premium cigars differently from other cigars.<sup>[13]</sup>
- *Public health considerations associated with premium cigars:* FDA requested studies or information regarding, among other things, and as compared to other cigars: (1) nicotine concentrations for premium cigars; (2) the risk of cancer,

heart disease, aortic aneurysm, periodontal disease, stroke, and chronic obstructive pulmonary disease associated with premium cigar use; (3) the addictiveness, and consumer perceptions of the addictiveness, of premium cigars; (4) the required warning statements for premium cigars; and (5) the applicable manufacturing, marketing, sale, distribution, advertising, and labeling and/or packaging requirements and restrictions in the FDCA and its implementing regulations and whether they should be applied differently to premium cigars.

Comments are due on the premium cigar ANPRM by June 25, 2018.

## Summary

An Advanced Notice of Proposed Rulemaking constitutes the earliest (and optional) stage of the administrative process that must be followed before eventually issuing an administrative rule. As such, there is still ample time for efforts to influence the FDA's regulatory approach to both premium cigars and tobacco product flavors by submitting comments to the administrative docket. Companies or individuals interested in providing such feedback should consult with counsel to determine the best approach to maximize their impact with FDA.

[1] See FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on Efforts to Reduce Tobacco Use, Especially Among Youth, by Exploring Options to Address the Role of Flavors - including Menthol - in Tobacco Products [here](#).

[1] Regulation of Flavors in Tobacco Products, 83 Fed. Reg. 12294 (Mar. 21, 2018);

[2] Regulation of Premium Cigars, 83 Fed. Reg. 12901 (Mar. 26, 2018).

[3] FDA News Release, FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of tobacco-related disease and death ([July 28, 2017](#)).

[4] 83 Fed. Reg. 12994, 12998-99 (Mar. 21, 2018).

[5] 83 Fed. Reg. 12999.

[6] *Id.*

[7] *Id.*

[8] 83 Fed. Reg. 12901, 12902 (Mar. 26, 2018).

[9] 83 Fed. Reg. 12902. (emphasis added).

[10] 83 Fed. Reg. 12902-03, *citing*, Catherine G. Corey, MPSH et al., *U.S. Adult Cigar Smoking patterns, Purchasing Behaviors, and Reasons for Use According to Cigar Type: Findings from the Population Assessment of Tobacco and Health (PATH) study, 2013-2014*, *Nicotine & Tobacco Research* (Sept. 15, 2017), available [here](#).

[11] Catherine G. Corey, MPSH et al., *U.S. Adult Cigar Smoking patterns, Purchasing Behaviors, and Reasons for Use According to Cigar Type: Findings from the Population Assessment of Tobacco and Health (PATH) study, 2013-2014*, *Nicotine & Tobacco Research* (Sept. 15, 2017), available [here](#).

[12] 83 Fed. Reg. 12903.

[13] 83 Fed. Reg. 12904.

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