

**FDA should extend the scope of the proposed flavor standard to prohibit flavors in all tobacco products, including e-cigarettes and smokeless tobacco, to make them less appealing to adolescents and young adults**

**Docket No. FDA-2021-N-1309  
for “Tobacco Product Standard for Characterizing Flavors in Cigars”**

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We generally support FDA’s proposed product standard prohibit flavors in cigars because it will reduce initiation rates of smoking cigars and will significantly reduce premature deaths and illnesses related to tobacco use. However, to meet its mandate to protect the public health, especially the health of adolescents and young adults, FDA should extend the scope of the proposed standard to prohibit flavors in all tobacco products, including e-cigarettes.

In the proposed rule, FDA requests comments regarding whether the scope of the product standard should be expanded to cover waterpipe and/or pipe tobacco in addition to cigars, and asks what advantages and/or disadvantages could be expected from extending the scope of the standard to include all combusted tobacco products, and whether there would be a risk that consumers would substitute and/or migrate to other combusted tobacco products if FDA limits the standard to cigars.<sup>1</sup> However, FDA does not consider expanding the scope to include e-cigarettes, smokeless tobacco, and other products, which do pose significant risks to consumers, especially adolescents and young adults, who are often motivated to try and continue to use these products due to their flavors.

Without providing scientific evidence, FDA states:

FDA is not including non-combusted tobacco products, such as ENDS [i.e., electronic nicotine delivery systems, e.g., e-cigarettes] and smokeless tobacco products, in the scope of this proposed standard. As discussed previously, characterizing flavors in a variety of tobacco products have appealing effects, particularly among youth and young adults. And youth and young adult use of any tobacco product remains a significant concern for FDA. However, at this time,

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<sup>1</sup> US Food and Drug Administration, Tobacco Product Standard for Characterizing Flavors in Cigars, May 4, 2022, Proposed Rule, 87 FR 26396 at 26435.

FDA is focusing this proposed rule on characterizing flavors in cigars because this action would help to prevent youth and young adults' use of combusted tobacco products. Combusted tobacco products are responsible for the majority of death and disease due to tobacco use.<sup>2</sup>

FDA is well aware of the overwhelming evidence that flavors in tobacco products attract and keep adolescent and young adult users. Indeed, a July 2022 paper<sup>3</sup> by Brian King, the current director of the Center for Tobacco Products, citing evidence from the 2021 National Youth Tobacco Survey (NYTS), states:

Flavors remain a major driver of youth e-cigarette use.<sup>4</sup> A majority of youths who currently use e-cigarettes report flavors are a reason they used the products, and in 2021, 84.7% of youths who used e-cigarettes reported using a flavored product<sup>4</sup>...

The 2021 NYTS reported that among students who reported using any tobacco product, 79.1% reported using flavored tobacco products, including 84.7% who used flavored e-cigarettes, 70.1% used flavored smokeless tobacco, 61.6% used flavored nicotine pouches, 46.6% used flavored hookahs (waterpipe), 44.4% used flavored cigars, 44.0% used flavored heated tobacco products, 38.8% used flavored (menthol only) cigarettes, and 34.4% used flavored pipe tobacco.<sup>4</sup> In other studies, adolescents report that they initiate with and continue to use e-cigarettes because they are available in flavors not found in traditional tobacco products.<sup>5, 6, 7, 8, 9, 10</sup>

Moreover, comprehensive measures that prohibit flavors in all tobacco products are necessary to reduce racial inequalities in tobacco-related disease. Use of flavored tobacco

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<sup>2</sup> US Food and Drug Administration, Tobacco Product Standard for Characterizing Flavors in Cigars, May 4, 2022, Proposed Rule, 87 FR 26396 at 26435.

<sup>3</sup> King BA. Flavors Remain a Major Driver of Youth E-Cigarette Use. *American Journal of Public Health*. 2022 Jul;112(7):999-1000.

<sup>4</sup> Gentzke AS, Wang TW, Cornelius M, et al. Tobacco product use and associated factors among middle and high school students—National Youth Tobacco Survey, United States, 2021. *MMWR Surveill Summ*. 2022;71(5):1–29. <https://doi.org/10.15585/mmwr.ss7105a1>

<sup>5</sup> Park-Lee E, Ren C, Sawdey MD & et al. 2021. Notes from the Field: E-Cigarette Use Among Middle and High School Students — National Youth Tobacco Survey, United States, 2021. *MMWR Morb Mortal Wkly Rep* 2021;70:1387–1389. DOI: <http://dx.doi.org/10.15585/mmwr.mm7039a4>.

<sup>6</sup> Gaiha, S. M., Lempert, L. K., McKelvey, K. & Halpern-Felsher, B. 2022. E-cigarette devices, brands, and flavors attract youth: Informing FDA's policies and priorities to close critical gaps. *Addictive behaviors*, 126, 107179.

<sup>7</sup> Goldenson, N. I., Leventhal, A. M., Simpson, K. A. & Barrington-Trimis, J. L. 2019. A review of the use and appeal of flavored electronic cigarettes. *Current addiction reports*, 6, 98-113.

<sup>8</sup> Leventhal, A. M., Goldenson, N. I., Cho, J., Kirkpatrick, M. G., McConnell, R. S., Stone, M. D., Pang, R. D., Audrain-McGovern, J. & Barrington-Trimis, J. L. 2019. Flavored e-cigarette use and progression of vaping in adolescents. *Pediatrics*, 144.

<sup>9</sup> Villanti, A. C., Johnson, A. L., Ambrose, B. K., Cummings, K. M., Stanton, C. A., Rose, S. W., Feirman, S. P., Tworek, C., Glasser, A. M., Pearson, J. L., Cohn, A. M., Conway, K. P., Niaura, R. S., Bansal-Travers, M. & Hyland, A. 2017. Flavored Tobacco Product Use in Youth and Adults: Findings From the First Wave of the PATH Study (2013-2014). *Am J Prev Med*, 53, 139-151.

<sup>10</sup> Pepper, J. K., Ribisl, K. M. & Brewer, N. T. 2016. Adolescents' interest in trying flavoured e-cigarettes. *Tob Control*, 25, ii62-ii66.

products is particularly common among Black and Hispanic/Latinx tobacco users of all tobacco products.<sup>11</sup>

Additionally, several recent papers demonstrate that flavors in tobacco products affect consumers' (and especially adolescents' and young adults') perceptions of these products. Flavors in e-cigarettes and flavors in smokeless tobacco cause youth to view those products with more curiosity and to consider them as being less dangerous.<sup>12</sup> Flavors in smokeless tobacco, notably wintergreen, may have direct effects on the brain that make the product more desirable and more addictive.<sup>13</sup> Regardless of the type of product, flavored tobacco is viewed as less harmful and is a common reason to try using a tobacco product.<sup>14</sup>

***The evidence is clear: flavors in any tobacco product – especially e-cigarettes and smokeless tobacco – attract adolescents and young adults to use these products.***

## **Conclusion**

While we generally support FDA's proposed product standard prohibiting characterizing flavors in cigars, the scope of the standard should also include non-combusted tobacco products. Flavored tobacco products of all types, especially flavored e-cigarettes and flavored smokeless tobacco, are especially appealing to adolescents and young adults and to Black and Hispanic/Latinx tobacco users. Comprehensive measures that prohibit flavors in *all* tobacco products are necessary to reduce youth use and racial inequalities in tobacco-related disease. Therefore, ***we urge FDA to expand the scope of the proposed product standard prohibiting flavors in cigars to include e-cigarettes, smokeless tobacco, heated tobacco, and all other tobacco products under FDA's jurisdiction.***

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<sup>11</sup> Watkins SL, Pieper F, Chaffee BW, Yerger VB, Ling PM, Max W. Flavored Tobacco Product Use Among Young Adults by Race and Ethnicity: Evidence From the Population Assessment of Tobacco and Health Study. *J Adolesc Health*. 2022 Aug;71(2):226-232. doi: 10.1016/j.jadohealth.2022.02.013. Epub 2022 May 9. PMID: 35550331.

<sup>12</sup> Chaffee BW, Couch ET, Urata J, Cash D, Werts M, Halpern-Felsher B. Electronic cigarette and moist snuff product characteristics independently associated with youth tobacco product perceptions. *Tob Induc Dis*. 2020 Aug 28;18:71. doi: 10.18332/tid/125513. PMID: 32934617; PMCID: PMC7485438.

<sup>13</sup> Rangel-Gomez M, Cruz-Cano R, Van Wagoner C, Kidanu A, McDonald CG, Clark PI. Dissociating the effect of flavor and nicotine in smokeless tobacco products using electroencephalography: The case of wintergreen flavors. *Addict Behav*. 2019 Apr;91:82-89. doi: 10.1016/j.addbeh.2018.11.013. Epub 2018 Nov 14. PMID: 30553545.

<sup>14</sup> Kowitz SD, Meernik C, Baker HM, Osman A, Huang LL, Goldstein AO. Perceptions and Experiences with Flavored Non-Menthol Tobacco Products: A Systematic Review of Qualitative Studies. *Int J Environ Res Public Health*. 2017 Mar 23;14(4):338. doi: 10.3390/ijerph14040338. PMID: 28333107; PMCID: PMC5409539.