



May 25, 2022

Dr. Robert Califf  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

RE: Docket No. FDA-2021-N-1309 Tobacco Product Standard for Characterizing Flavors in Cigars  
– Opposing Extension of the Comment Period

Dear Dr. Califf:

Today, we write in response to several requests the Food and Drug Administration (FDA) received to extend the public comment period for the proposed rule to remove all characterizing flavors, except for tobacco, from cigars. We strongly oppose any extension of the comment period, and we urge FDA to deny any such requests.

FDA has been reviewing the role of flavors in tobacco products generally, and cigars specifically for many years. Indeed in 2018, FDA opened an Advanced Notice of Proposed Rulemaking on flavored tobacco generally, which included flavored cigars. FDA received more than 525,000 comments on this docket. Further FDA has conducted its own review of the scientific literature on flavored cigars.<sup>1</sup> The proposed rule under consideration today is long overdue, and allowing flavored products like cigars to stay on the market is antithetical to the protection of public health, the standard by which FDA must view actions on tobacco products. A 60-day comment period is appropriate and sufficient to provide the information requested, particularly since this is at least the second public comment period covering this topic. All interested parties should have more than adequate time to prepare their responses in the current time frame.

However, the 960,000 middle and high school students who have smoked cigars in the last 30 days<sup>2</sup> – more than half of which (58.3%) used flavored cigars<sup>3</sup> – do not have the luxury of time. Nor do the 3,163 young adults who try a cigar every day.<sup>4</sup> We know that flavors in cigars attract youth and young adults to these products, which in turn results in an increased likelihood that they will progress to regular cigar smoking. Further, as FDA notes in the proposed rule, youth and young adults, racial minorities, those with low-income, and those in the LGBTQ population are disproportionately impacted by cigars with higher prevalence and use rates, higher frequency of use, all of which lead to tobacco-related health disparities.<sup>5</sup> Removing flavors from cigars will do much to reduce the appeal of these products and therefore reducing the 9000 deaths they cause each year.<sup>6</sup> Extending the comment period leaves these products on the market, causing more damage with each day.

The public health threat posed by flavored cigars requires speedy action by FDA to remove these products from the market. Allowing an additional extension at this stage is unacceptable. We appreciate your consideration and urge FDA to deny all requests to extend the comment period.

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<sup>1</sup> FDA, “Scientific Assessment of the Impact of Flavors in Cigar Products.” Silver Spring, MD: HHS, FDA, Center for Tobacco Products, 2022.

<sup>2</sup> Gentzke, A.S., T.W. Wang, A. Jamal, et al., “Tobacco Product Use Among Middle and High School Students—United States, 2020.” *Morbidity and Mortality Weekly Report*, 69(50):1881–1888, 2020. Available at <http://dx.doi.org/10.15585/mmwr.mm6950a1>

<sup>3</sup> Parns, T.A., S.K. Head, M.D. Sawdey, et al., “Characteristics of Past 30-Day Cigar Smoking, U.S. Adolescents, 2020.” *American Journal of Preventive Medicine*, 62(1):e39–e44, 2022. Available at <https://doi.org/10.1016/j.amepre.2021.06.011>.

<sup>4</sup> Substance Abuse and Mental Health Services Administration (SAMHSA), Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health. HHS Publication No. PEP20–07–01–001, NSDUH Series H–55. Rockville, MD: HHS, SAMHSA, Center for Behavioral Health Statistics and Quality, 2020. Available at [https://store.samhsa.gov/sites/default/files/SAMHSA\\_Digital\\_Download/PEP20-07-01-001-PDF.pdf](https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/PEP20-07-01-001-PDF.pdf)

<sup>5</sup> Tobacco Product Standard for Characterizing Flavors in Cigars. Docket No. FDA-2021-N-1309. <https://www.regulations.gov/document/FDA-2021-N-1309-0001>

<sup>6</sup> Nonnemaker, J., B. Rostron, P. Hall, et al., “Mortality and Economic Costs from Regular Cigar Use in the United States, 2010.” *American Journal of Public Health*, 104(9):e86–e91, 2014. Available at <https://doi.org/10.2105/AJPH.2014.301991>.

Please contact Stacey Gagosian ([sgagosian@truthinitiative.org](mailto:sgagosian@truthinitiative.org)), Managing Director of Public Policy at Truth Initiative if you have questions.

Sincerely,

Action on Smoking and Health  
African American Tobacco Control Leadership Council  
American Academy of Pediatrics  
American Cancer Society Cancer Action Network  
American Heart Association  
American Lung Association  
Americans for Nonsmokers' Rights  
Asian Pacific Partners for Empowerment, Advocacy and Leadership  
Campaign for Tobacco-Free Kids  
Center for Black Health and Equity  
Counter Tools  
National LGBT Cancer Network  
Parents Against Vaping E-cigs  
Public Health Law Center  
Truth Initiative

CC: Michele Mital, Acting Director, Center for Tobacco Products, Food and Drug Administration