



Summary of Cigar Association of America, Inc. November 6, 2023, Meeting with the Office of Management and Budget re FDA’s Product Standard: Characterizing Flavors in Cigars

Cigar Association of America, Inc. (“CAA”) is the leading national trade organization representing the interests of cigar manufacturers, importers, distributors, and major suppliers of the industry and its members manufacture and distribute the vast majority of the flavored cigars – mass market and premium -- sold in the United States.

The Office of Management and Budget (“OMB”) has twice rejected FDA’s efforts to remove flavored cigars from the market – in 2016 and in 2019 – both times apparently determining that the purported public health benefits from such a restriction did not outweigh its catastrophic economic consequences. OMB was correct then, and FDA’s justifications for prohibition have even less basis today than they did then. The Flavored Cigar Product Standard continues to be a solution in search of a problem, and it should be withdrawn.

In order to enact a product standard, the Tobacco Control Act requires FDA to consider (i) whether the potential product standard is appropriate for the public health, taking into consideration scientific evidence concerning the risks and benefits to the *population as a whole*; (ii) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (iii) the increased or decreased likelihood that those who do not use tobacco products will start using such products. The Flavored Cigar Product Standard fails on all three accounts.

FDA rests the need for the Flavored Cigar Product Standard on claims (i) regarding youth usage of cigars; and (ii) that prohibiting flavored cigars will address health disparities in minority sub-populations of adults. As shown below and in documents submitted to OMB, both arguments fail.

*First*, youth usage rates of cigars, and of flavored cigars in particular, are at all-time lows, and these low rates reflect a stable and sustained trend. The 2022 National Youth Tobacco Survey (“NYTS”) showed past 30-day youth cigar use at 1.85% and past 30-day youth flavored cigar use at 0.83%. The 2023 NYTS data showed past 30-day youth cigar use at 1.6% and, while the flavored cigar use data has not yet been released, it is reasonable to assume it will follow the trend at under 1% of use. As FDA acknowledged in its press release announcing the NYTS data, “declines in current use were also observed during 2022-2023 for cigars and overall combustible tobacco smoking, representing all-time lows.” The most recent data from the Population Assessment of Tobacco and Health Survey (PATH) shows past 30-day youth usage of cigars at 0.70% and past 30-day youth usage of flavored cigars at 0.14%. The public health accomplishment of sustained, almost non-existent youth usage rates of flavored cigars should be lauded, not used as a pretext to prohibit an entire category of products.





*Second*, FDA claims that prohibiting flavored cigars will address health disparities in certain adult sub-populations, namely Black, Non-Hispanic Americans. But again, FDA fails to demonstrate that flavored cigars are associated with such health disparities or that removing them would remedy the disparities. The most recent wave of PATH data, Wave 6, reports that, in the overall adult population, Black, Non-Hispanic use of flavored cigars had fallen to 1.86% from 3.22% in Wave 5. Further, in the young adult population (18–25-year-olds) the past 30-day prevalence rate had fallen to 0.76% in Wave 6 from 1.57% in Wave 5. FDA’s claims aside, there is simply not a pattern of use of these products that raises a concern of public health that can justify eliminating an entire category of products.

Both of FDA’s stated reasons for the Flavored Cigar Product Standard fail; however, that is not the end of the analysis. If the Flavored Cigar Product Standard is finalized it would be catastrophic to the economy. Below are merely some of the major economic impacts of the rule – which under any standard make this an “economically significant” rule. These are outlined in further detail in the two reports by Policy Navigation Group that CAA has submitted with this document.

- Losses of over \$750 million in federal, state, and local tax revenue;
- Over a 32% reduction in cigar sales representing over 4 billion cigars and \$3.8 billion to the economy;
- A loss of 16,000 jobs and over \$840 million in wages;
- Rise in illicit trade and enforcement costs placed on state and local governments; and
- Huge economic impacts to the Dominican Republic, Nicaragua and Honduras.

Finally, the Flavored Cigar Product Standard as written is legally flawed. *First*, the definition of “characterizing flavor” is unconstitutionally vague by not providing regulated entities proper notice of what would and would not be prohibited by the Rule. *Second*, the Rule violates both First and Fifth Amendment by likely disallowing the use of certain trademarks and infringing on speech by prohibiting “implicit flavor representations.” *Third*, a Rule of this economic consequence is reserved to Congress under the Major Questions Doctrine. *Fourth*, the Rule does not follow the requirements for a product standard – namely it does not look at the population as a whole, but only certain adult sub-populations. *Fifth*, FDA did not consider any less restrictive alternatives to the prohibition an entire category of products. And finally, *sixth*, FDA did not consider the vast unintended consequences of this Rule on illicit trade or the inevitable social justice consequences that will stem from enforcement of state laws in relation to this rule.

The Flavored Cigar Product Standard is not supported by science, economics, or law. It must be withdrawn.





CAA submits the following documents for consideration along with this summary:

- Consilium Sciences, Evaluation of Health Equity and Health Disparity Factors in the Context of Flavored Cigars, September 14, 2023
- Consilium Sciences, Evaluation of Flavored Cigar Products as They Relate to Questions of Public Health– Supplement to October 2020 Report, July 29, 2022
- Consilium Sciences, Evaluation of Flavored Cigar Products as They Relate to Questions of Public Health– Supplement #2 to October 2020 Report, November 6, 2023
- Consilium Sciences, Review of the Evidence on Flavored Cigars, July 2022
- Commonwealth of Massachusetts, Annual Report of Multi-Agency Illegal Tobacco Task Force, February 28, 2023
- Policy Navigation Group, Economic Impacts of FDA’s Proposed Rule, Tobacco Product Standard for Characterizing Flavors in Cigars, July 2022
- Policy Navigation Group, Supplemental Report on the Economic Impacts of FDA’s Proposed Rule, Tobacco Product Standard for Characterizing Flavors in Cigars, February 8, 2023
- Tax Foundation, Californians Still Smoking Menthol after Ban: Evidence from a Discarded Pack Audit, October 26, 2023
- Tax Foundation, FDA Ban on Flavored Cigars Could Cost \$836 Million in Annual Excise Tax Revenue, August 17, 2022

