December 18, 2024

The Premium Cigar Association
513 Capitol Court NE, Suite 300
Washington, D.C. 20002

Office of Management and Budget
Attn: Office of Information and Regulatory Affairs
Executive Office of the President
725 17th Street NW
Washington, D.C. 20503

RE: Exclusion of Premium Cigars from Tobacco Product Standard for Nicotine Level of Certain Tobacco Products (RIN: 0910-AI76)

To Whom It May Concern –

The Premium Cigar Association (PCA) represents over 3,000 retail members who collectively employ more than 40,000 people in the United States and roughly 300 associate member premium cigar and pipe tobacco manufacturers. For the reasons set forth below, PCA urges the Office of Management and Budget to ensure that the Food and Drug Administration (FDA) acknowledges and expressly excludes premium cigars from the scope of its proposed rule entitled "Tobacco Product Standard for Nicotine Level of Certain Tobacco Products" (the Proposed Rule).

Importantly, from a procedural perspective, FDA lacks the legal authority to establish the proposed product standard as applied to premium cigars since premium cigars no longer qualify as FDA-regulated tobacco products.[1] Accordingly, the Proposed Rule necessarily would not apply to "premium cigars," as the U.S. District Court for the District of Columbia defined this product category in its August 19, 2020, order in *Cigar Ass'n of Am.* For this reason alone, and for the sake of clarity within the industry, FDA should explicitly state in the Proposed Rule that it would not apply to premium cigars.

Moreover, in the event of any change in the regulatory status of premium cigars under Chapter IX of the Federal Food, Drug, and Cosmetic Act (for example, due to a

[1] On August 9, 2023, the U.S. District Court for the District of Columbia vacated the Deeming Rule as applied to premium cigars based on the court's earlier finding that FDA acted arbitrarily and capriciously in including premium cigars within the scope of the Deeming Rule. *See Cigar Ass'n of Am. et al. v. U.S. Food & Drug Admin.*, Case No. 16-CV-01460, Doc. 276 (D.D.C., Aug. 9, 2023).

successful appeal by FDA of the U.S. District Court for the District of Columbia's August 9, 2023, order or through new notice-and-comment rulemaking), the Proposed Rule, if finalized, should not automatically take effect as applied to premium cigars. Instead, FDA should need to proceed through notice-and-comment rulemaking to propose amending any final rule to extend to premium cigars so that FDA and industry can assess whether, pursuant to a rigorous evaluation of scientific evidence, the proposed product standard as applied to premium cigars meets the statutory requirements, including that the rule would be "appropriate for the protection of public health."

Separately, from a substantive perspective, scientific evidence does not support that application of the Proposed Rule to premium cigars would be appropriate for the protection of public health. The following examples from the NASEM Report[2] and data from the PATH Study[3] support this contention:

1. **Distinct Patterns of Use –** Premium cigars are used distinctly from other tobacco products. The NASEM Report concluded that most premium cigar smokers engage in infrequent use, with a significant proportion smoking fewer than two cigars per month. See NASEM Report, pp. 123-127. Data derived from the PATH Study reveal that the median consumer of premium cigars used these products on 1.7 of the past 30 days and smoked 0.1 cigars per day; only 6.7% of premium cigar consumers used these products daily.[4] This level of consumption is markedly lower than that of cigarettes and other tobacco products, and it presents significantly lower risk of dependence by users. These patterns of use are not consistent with use of premium cigars to satisfy a nicotine addiction or otherwise as a nicotine delivery method, and FDA has observed that nicotine delivery appears to drive the frequency of tobacco use.[5] Instead, premium cigars are generally used as luxury goods reserved for occasional indulgence primarily by older and wealthier adults.

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[2] "NASEM Report" refers to the 2022 report issued by the National Academies of Sciences, Engineering, and Medicine (NASEM) and commissioned by FDA and the National Institutes of Health (NIH). *See* NASEM, Premium Cigars: Patterns of Use, Marketing, and Health Effects (2022).

[3] "PATH Study" refers to the national longitudinal study of tobacco use commissioned by FDA and NIH. *See* FDA and NIH Study: Population Assessment of Tobacco and Health (content current as of Oct. 16, 2024), https://www.fda.gov/tobacco-products/research/fda-and-nih-study-population-assessment-tobacco-and-health (providing, among other things, information on data access and availability).

[4] *See* Catherine G. Corey 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 Res., Sept. 15, 2017, at 5 tbl. 2. Although this paper assessed data from only Wave 1 of the study, this general pattern has remained true across all Waves to date.

[5] *See, e.g.*, 83 Fed. Reg. 11818, 11823-24 (March 16, 2018).

2. **Low Prevalence Among Youth –** Youth initiation of premium cigars is negligible. Data from the PATH Study show virtually no uptake of premium cigars among individuals aged 12 to 17 years.[6] Premium cigars are not marketed or designed to appeal to youth, as recognized by both industry practice and public health data.

3. **Negligible Health Risks at Typical Use Levels –** The NASEM Report highlights the lack of robust evidence linking premium cigar use to significant health risks when consumed infrequently, as is typical of most users. See NASEM Report, pp. 225-228. The patterns of use do not align with sustained exposure to nicotine and other compounds that characterize cigarette smoking.

4. **Economic and Cultural Importance –** Premium cigars represent a vital cultural and artisanal product, supporting tens of thousands of jobs and small businesses in the United States. Overregulation would devastate this industry without measurable public health benefits, as recognized in economic analyses (Economic Impact from the Proposed Tobacco Tax Equity Act of 2021; pages 15-18).

5. **Lack of Evidence for Nicotine Reduction Effectiveness in this Context –** Reducing nicotine levels in premium cigars would likely have no significant impact on public health outcomes due to the infrequent and celebratory nature of their use. Moreover, the patterns of use described above, as well as the defining features of premium cigars such as their all-natural and handmade character, suggest that premium cigars are extraordinarily unlikely candidates for migration following implementation of any nicotine-level standard for cigarettes. The NASEM Report underscores the necessity of tailoring regulatory policies to product-specific use patterns and risks. See NASEM Report, pp. 315-320.

Last, premium cigars could not feasibly comply with a tobacco product standard that imposes a maximum nicotine level. By definition, premium cigars contain only tobacco leaf (grown, cured, and aged naturally) and a small amount of vegetable adhesive. In addition, the tobacco leaf in each premium cigar is selected by a master tobacconist to achieve a specific sensory profile, and adult consumers seek out premium cigars for these very qualities. PCA is not aware of any means of reducing nicotine levels in natural tobacco leaf that would preserve the integrity of the premium cigar manufacturing process. Chemical extraction and bioengineering are fundamentally incompatible with the concept of a premium cigar. Accordingly, to include premium cigars within the scope of the Proposed Rule would fundamentally ignore the nature and characteristics of this product category.

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[6] *See, e.g.*, Kasza, K. A. et al. (2023). National longitudinal tobacco product discontinuation rates among US youth from the PATH Study: 2013–2019 (waves 1–5), Tobacco Control, pp. 24-30 https://doi.org/10.1136/tc-2022-057729.

For the foregoing reasons, we respectfully request your assistance in ensuring that FDA explicitly excludes premium cigars from the scope of the Proposed Rule. Including premium cigars would not align with the law or sound regulatory principles, as doing so would fail to recognize their distinct usage patterns, minimal youth appeal, and negligible public health risks.

The Premium Cigar Association remains committed to working with federal agencies to ensure that regulatory policies comply with applicable laws and are evidence-based and effectively target products that pose significant public health concerns.

Thank you for considering our perspective on this critical matter. We are available to provide additional data or testimony to support this request.

Respectfully,

Joshua Habursky
Chief Executive Officer/Executive Director
Premium Cigar Association