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Via CTP Portal

Mitch Zeller, J.D.
Director, Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Docket No. FDA-2019-N-3065 (84 Fed. Reg. 42,754, August 16, 2019) – Letter on “Tobacco Products; Required Warnings for Cigarette Packages and Advertisements Proposed Rule”

Director Zeller:

Altria Client Services LLC (“ALCS”), on behalf of Philip Morris USA Inc. (“PM USA”) and Sherman Group Holdings, LLC and its subsidiaries (“Nat Sherman”)¹ write to address the recent opinion by Judge Mehta of the United States District Court for the District of Columbia in *Cigar Association of America, et al., v. FDA*² and its relevance to the proposed graphic health warning rule and the heat-not-burn IQOS® and HeatSticks® products.³

In the *Cigar Association* case, the Court examined the studies FDA used to justify extending the Tobacco Control Act’s warning requirements to premium cigars.⁴ In ruling that FDA failed to meet its burden under the Administrative Procedure Act (“APA”), the Court rejected FDA’s attempt to use scientific studies about non-premium cigars or other tobacco products to justify regulatory action on premium cigars, a different category of tobacco product with different use patterns. The Court found that FDA failed to provide data specific to *premium* cigars or explain why data on other categories of cigars were applicable to premium cigars:

¹ PM USA and Nat Sherman are wholly-owned subsidiaries of Altria Group, Inc. (“Altria”). PM USA manufactures cigarettes and is licensed to sell and distribute IQOS® and HeatSticks® in the United States and Nat Sherman sells premium cigars and manufactures and sells super premium cigarettes. ALCS provides certain services, including regulatory affairs, to the Altria family of companies. “We” and “our” are used throughout to refer to PM USA and Nat Sherman.

² *Cigar Association of America, et al., v. FDA*, Nos. 1:16-cv-01460, 1:18-cv-01797, (D.D.C. Feb. 3, 2020).

³ 84 Fed. Reg. 42,754 (August 16, 2019).

⁴ 81 Fed. Reg. 28,974 (May 10, 2016).

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“FDA does not, for example, explain . . . why informational concerns generally attendant to cigar or other tobacco consumption obtain with respect to premium cigars . . . [T]he most that can be said about [FDA’s cited] portion of the Proposed Deeming Rule is that it relies upon evidence to justify the warning regime that does not apply to premium cigars and their users.”⁵

In addition, the Court critiqued FDA’s reliance on a study that “subsumed multiple types of cigars under the term ‘cigar,’ and thus . . . did not differentiate between types of cigars used by the participants,”⁶ and observed that “the agency did not *separately* consider whether users or prospective users of premium cigars in fact harbor misconceptions about the product [.]...”⁷

The Court’s decision makes clear that the APA requires FDA to use data specific to the tobacco product category it intends to regulate. Accordingly, FDA’s proposed rule on graphic health warnings violates the APA because FDA does not identify *any* heat-not-burn category specific data. Indeed, FDA has recognized that traditional cigarettes and heat-not-burn “cigarettes” have different risk profiles. After a comprehensive scientific review, FDA authorized the marketing of IQOS® and three HeatSticks® products and concluded that they are “likely to lead to less risk of tobacco-related diseases” and have “the potential for a relative benefit” for smokers as compared to traditional cigarettes.

The proposed graphic health warning rule, however, did not address any information related to heat-not-burn products, including the accuracy of the proposed warnings for this category or whether a need existed for those warnings to overcome consumer misconceptions of the health risks of heat-not-burn products. Instead, FDA relies on data relevant only to combustible cigarettes. The Court in *Cigar Association* rejected this approach.

For the reasons noted above and in our prior comments to the docket,⁸ we urge FDA to exempt IQOS® and HeatSticks® from the final graphic health warning rule.

If you have any questions, please contact me at (804) 335-2034.

Sincerely,



⁵ *Cigar Association*, at 25.

⁶ *Id.* at 26.

⁷ *Id.* at 28. Emphasis added.

⁸ ALCS Comments to FDA-2019-N-3065, Oct. 15, 2019, Nov. 27, 2019. Available at <https://www.regulations.gov/document?D=FDA-2019-N-3065-0450>; <https://www.regulations.gov/document?D=FDA-2019-N-3065-0584>.