UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CIGAR ASSOCIATION OF AMERICA et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**Case No. 16-cv-01460 (APM)**
	)	
UNITED STATES FOOD AND DRUG ADMINISTRATION et al.,	)	
	)	
Defendants.	)	

ORDER

I.

This (hopefully) is the final chapter in this decade-long dispute between makers of premium cigars and Defendant U.S. Food and Drug Administration (FDA). In 2016, the FDA exercised its "deeming" authority under the 2009 Family Smoking Prevention and Tobacco Control Act to regulate all cigar products ("Deeming Rule"). *See Cigar Ass'n of Am. v. FDA* (*Cigar II*), 132 F.4th 535, 537–38 (D.C. Cir. 2025). After years of litigation, this court in 2023 vacated the Deeming Rule as applied to a category of products known as "premium cigars." *See Cigar Ass'n of Am. v. FDA* (*Cigar I*), No. 16-cv-1460, 2023 WL 5094869, at *6 & n.7 (D.D.C. Aug. 9, 2023). To effectuate the ruling, the court had to distinguish between those cigar products that remained subject to the Deeming Rule and those no longer within its purview. *See id.* Borrowing from a definition of "premium cigars" that the FDA offered in a related case, the court defined "premium cigars" as those cigars that: (1) are wrapped in whole tobacco leaf; (2) contain a 100 percent leaf tobacco binder; (3) contain at least 50 percent (of the filler by weight) long filler tobacco; (4) are handmade or hand rolled; (5) have no filter, nontobacco tip, or nontobacco

mouthpiece; (6) do not have a characterizing flavor other than tobacco; (7) contain only tobacco, water, and vegetable gum with no other ingredients or additives; and (8) weigh more than six pounds per 1,000 units. *Id.* at *6 n.7.

The D.C. Circuit affirmed this court's vacatur of the Deeming Rule as it relates to "premium cigars." *Cigar II*, 132 F.4th at 540–41. But the Circuit also ruled that this court should have sought the parties' input before adopting a definition of the term. *Id.* at 543. So, it reversed and remanded for the limited purpose of "invit[ing] briefing on the appropriate definition of 'premium cigars' before entering a final order." *Id.* On remand, the court invited briefing as instructed. Having now considered the parties' positions, the court adopts the same definition of "premium cigars" it did before and enters this final order vacating the Deeming Rule as to cigar products covered by that definition.

II.

A.

Among the parties, only Plaintiff Cigar Association of America ("CAA") seeks to modify the definition of "premium cigars." It asks the court to eliminate three of the eight definitional components: (1) the vegetable gum ingredient restriction and the bar on additives; (2) the "long filler" requirement; and (3) the "characterizing flavor" restriction. *See* Br. of CAA in Resp. to the Court's May 12, 2025 Order, ECF No. 286 [hereinafter CAA Br.], at 10–19. CAA generally argues that these "elements of the [court's definition], in addition to arbitrarily favoring one type of 'premium cigar' in the marketplace, are undefined and subjective, thereby further complicating FDA enforcement." *Id.* at 9. More specifically, as to the first alteration, they protest that restricting the adhesive to vegetable gum excludes other types of adhesives used to make premium cigars, *id.* at 10, and that the restriction on additives could inadvertently impact "long-standing part[s] of

premium cigar manufacturing" such as color fasting, *id.* at 11. They assert that the "long filler" requirement is "impossible to verify post-manufacturing." *Id.* at 11–12. And, as to the restriction on "characterizing flavor," CAA complains that the phrase is undefined and could be difficult to administer, *id.* at 12–15, and it urges that because youth so infrequently use premium cigar products, lifting the restriction will not increase smoking initiation among that demographic. *Id.* at 15–17.

The FDA opposes these proposed changes. Despite arguing on appeal that this "court's remedy usurped the FDA's role" in defining "premium cigars," *Cigar II*, 132 F.4th at 542–43, the agency now wants to keep the eight-point definition intact, *see* Defs.' Supp. Br. Regarding the Definition of "Premium Cigars," ECF No. 293 [hereinafter Defs.' Br.], at 4. It points to both practical and public health-related reasons for its position. As to administrative challenges, the FDA emphasizes that it has used the court's definition to "implement and enforce [Tobacco Control Act] requirements," including the statutory user fee program. *Id.* at 6–7. It also has relied on that definition "in several agency regulations and other rulemaking documents," and so too have industry participants. *Id.*; *see also* Defs.' Br., Decl. of Michele Mital, ECF No. 293-1 [hereinafter Mital Decl.], ¶ 5 ("[T]he eight-point definition has been the agency's operative 'premium cigar' definition for several years, used by both the agency and regulated parties in multiple contexts."); *id.* ¶¶ 7, 9–12, 15–21. As to public health concerns, the FDA says that CAA's proposed changes raise scientific and policy questions better decided by agency subject-matter experts through the rulemaking process. Defs.' Br. at 8–10; Mital Decl. ¶¶ 22–32.

Two other plaintiff groups—Premium Cigar Association and Cigar Rights of America—also oppose any modification for public health and market-related reasons. *See* Pls. Premium

Cigar Ass'n and Cigar Rights of Am.'s Resp. Regarding the Definition of Premium Cigars, ECF No. 294 [hereinafter PCA Br.], at 8–20.

B.

The court declines to adopt CAA's proposed alterations. "[T]his court is duly deferential to the burdens under which administrative agencies must operate, and recognizes that courts should not disrupt their timetables and priorities lightly." *Cobell v. Norton*, 240 F.3d 1081, 1107 (D.C. Cir. 2001). The FDA and regulated parties have relied on the court's definition of "premium cigars" for years, and CAA does not dispute that its proposals would adversely impact the agency's administrative responsibilities and rulemaking efforts. Its principal retort is that these difficulties are of "FDA's own making." CAA Br. in Further Supp. of a Definition of Premium Cigar, ECF No. 301, at 10. But that is not right. True, the FDA acted arbitrarily and capriciously in applying the Deeming Rule to "premium cigars," but by deciding to regulate *all* cigars it had no reason to distinguish between regulated and unregulated cigar products. The need for a firm definition arose only because of this court's ruling. The definitional problem is of this court's making, not the FDA's.

The court also agrees with the agency that, if a definitional refinement is appropriate, rulemaking, not judicial fiat, is the better way to achieve it. Unlike the FDA, this court lacks the expertise to rigorously evaluate the public health consequences of CAA's proposed changes. *See Nat'l Wildlife Fed'n v. EPA*, 286 F.3d 554, 560 (D.C. Cir. 2002) ("[P]articular deference is given by the court to an agency with regard to scientific matters in its area of technical expertise."). The FDA has convincingly shown that the suggested modifications would attract substantial public commentary. The agency's subject-matter experts would use those comments to "make a reasoned decision that protects the public health and accounts for risks and benefits to both users and non-

users of tobacco products." Mital Decl. ¶ 22. By way of example, the FDA has had long-standing concerns about the role of characterizing flavors in tobacco-use initiation by youth. *See id.* ¶¶ 25–26. CAA's assertion that lifting the flavoring restriction would not encourage youth tobacco use because studies show that youth do not use premium cigars, CAA Br. at 15–17, is precisely the type of scientific and policy judgment the FDA is better suited to make after a thorough evaluation of the evidence and public comments. That is not where this court's competence lies.

In any event, the court also is unpersuaded by CAA's rationales for its proposed changes. Start with its request to lift the requirement that a premium cigar product "contain only tobacco, water, and vegetable gum with no other ingredients or additives." CAA Br. at 3. CAA argues that "vegetable gum" is a type of adhesive, but there are other types used to make premium cigars that might not qualify as "vegetable gum." *Id.* at 10 & n.14 (observing that "pectin" adhesives, made from both fruits and vegetables, may not be considered "vegetable gum"). It also argues that certain common manufacturing techniques could be viewed as introducing "additives." *Id.* at 11 (identifying additives used to "color fast" cigars, placement of cigars in cedar sleeves, and aging in barrels or wood containers). But this latter concern does not justify eliminating the restriction on additives altogether, as doing so would open the door to possible chemical manipulations. *See* PCA Br. at 8–10. And CAA has not identified any instance of regulatory or industry confusion arising from these product limits. *See* CAA Br. at 9–11; Decl. of Antonio Gutierrez Hildago, ECF No. 287, ¶¶ 7–11.

Similarly, CAA believes the "long filler" requirement is too hard to administer. CAA Br. at 11–12. But CAA has not identified any example of the FDA disqualifying a cigar product as "premium" because it lacks the appropriate "long filler" percentage or of a market participant

expressing uncertainty as to whether its product has met the 50-percent standard. CAA's worries about administering the "long filler" requirement appear largely hypothetical.

Finally, CAA's haste to do away with the restriction on "characterizing flavor" sweeps so broadly that it would allow for premium cigars to contain any type of flavoring, regardless of the public health implications and its compatibility with the product category. *See* CAA Br. at 12–15. The evidentiary record as to flavoring and premium cigars is wholly undeveloped. The court will not remove this critical element of the definition based largely on CAA's say-so.

III.

For the foregoing reasons, the court enters this final Order vacating the Deeming Rule as it relates to "premium cigars," as defined by the court's decision in *Cigar I*. This is a final, appealable order.

Dated: April 15, 2026

Amit P. Mehta
United States District Judge