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Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2017-N-6189

Dear Sir or Madam:

The International Premium Cigar & Pipe Retailers Association (“IPCPR”) submits these comments in response to the Advance Notice of Proposed Rulemaking (“ANPRM”) issued by the U.S. Food and Drug Administration (the “FDA”) regarding the development of a tobacco product standard for the nicotine level of cigarettes.¹ Among other topics, the FDA requests comments and information on the scope of a prospective nicotine-level standard, specifically naming premium cigars as a class of tobacco products potentially meriting exclusion.² IPCPR commends the FDA for recognizing that premium cigars are made and used differently than all other tobacco products and believes that those differences make a nicotine-level standard for premium cigars both unnecessary and infeasible. To that end, the agency should consider, in addition to the comments and data submitted in response to this rulemaking docket, information submitted on the parallel rulemaking docket addressing premium cigars. IPCPR urges the FDA not to extend any tobacco product standard for nicotine levels to premium cigars.

Based in Washington, D.C., IPCPR is a not-for-profit trade group representing premium cigar and tobacco retail shops located throughout the United States and abroad. IPCPR, formerly the Retail Tobacco Dealers of America, was established in 1933. Its retail members are small businesses, typically family-owned and operated. IPCPR members operate more than 3,000 retail stores, employ more than 20,000 people, and sell premium tobacco products, including handmade cigars and pipe tobacco, to scores of adult customers nationwide. IPCPR also has a direct economic relationship with more than 350 manufacturers, distributors, and service providers in the tobacco industry. Many of these partners are also

¹ Tobacco Product Standard for Nicotine Level of Combusted Cigarettes, 83 Fed. Reg. 11,818 (Mar. 16, 2018).

² *Id.* at 11,826.

small businesses and employ an estimated 7,000 additional people in the United States and thousands more abroad, primarily in Latin America.

I. Statutory and Regulatory Background

Section 907 of the Family Smoking Prevention and Tobacco Control Act (the “TCA”) authorizes the FDA to issue a tobacco product standard *if* the Secretary of the Department of Health and Human Services (the “Secretary”) makes an express finding that such a standard “is appropriate for the protection of public health.”³ In making this finding, the Secretary must consider “scientific evidence” on three topics: (1) “the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard”; (2) “the increased or decreased likelihood that existing users of tobacco products will stop using such products”; and (3) “the increased or decreased likelihood that those who do not use tobacco products will start using such products.”

In this ANPRM, the FDA seeks information to “develop[] a tobacco product standard to set the maximum nicotine level for cigarettes.”⁴ Consistent with its acknowledgment that combustible cigarettes reside at the most dangerous end of the “continuum of risk,”⁵ the FDA appropriately has focused this ANPRM on cigarettes, with only peripheral attention to other tobacco products. Indeed, the FDA’s ultimate objective is to “[g]reatly reduc[e] or eliminat[e] the addictiveness of cigarettes,”⁶ which the agency has characterized as “one of our nation’s greatest public health challenges.”⁷ To the extent the agency is considering extending the nicotine standard to other tobacco products, its stated concerns motivating such an extension are migration of cigarette users to other tobacco products and dual usage of cigarettes and another tobacco product.⁸ Properly defined, premium cigars implicate neither issue: The scientific evidence is clear that premium cigars are not used to feed a nicotine addiction or otherwise for nicotine delivery or as complements to cigarettes. Accordingly, excluding premium cigars from any nicotine level standard would not lead to any weakening of a nicotine standard for cigarettes through the potential migration or dual use mechanisms identified by the agency.

II. Premium Cigars Should Be Excluded from Any Nicotine Level Standard

Premium cigars, by their very nature, are not cigarette substitutes. They contain only tobacco leaf and an adhesive, they are made by hand rather than through mechanization, and they cost far more and are used far less frequently than other tobacco products.

A. Definition of Premium Cigars

When weighing a regulatory exemption for premium cigars, the FDA identified seven essential features of the definition of a premium cigar, which IPCPR endorses: (1) it is wrapped in whole tobacco leaf; (2) it contains a 100 percent leaf tobacco binder; (3) it contains primarily long filler tobacco; (4) it is

³ 21 U.S.C. § 387g(a)(3)(A).

⁴ 83 Fed. Reg. at 11,818.

⁵ See Press Release, FDA, FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death (July 28, 2017), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm568923.htm> (“A key piece of the FDA’s approach is demonstrating a greater awareness that nicotine—while highly addictive—is delivered through products that represent a continuum of risk and is most harmful when delivered through smoke particles in combustible cigarettes.”).

⁶ 83 Fed. Reg. at 11,818.

⁷ *Id.* at 11,825.

⁸ *Id.*



made by combining manually the wrapper, filler, and binder; (5) it has no filter, tip, or non-tobacco mouthpiece and is capped by hand; (6) it does not contain an additive that is a characterizing flavor other than tobacco; and (7) it weighs more than 6 pounds per 1,000 units.⁹ IPCPR will address the proper definition of premium cigars in forthcoming comments for the FDA’s ANPRM on the regulation of premium cigars (the “Premium Cigar ANPRM Comments”).¹⁰ In those comments, we will urge the FDA to omit an eighth factor: a minimum retail price requirement, which we believe will be practically unadministrable. It would be very difficult to create a *manufacturing* standard based on the price at which a product is sold by a *retail* establishment. In any event, the required method of construction for premium cigars—that they are made entirely by hand—ensures that they can neither be produced nor profitably sold cheaply. It is worth noting that FDA staff, when publishing the below-referenced study of premium cigars in *Nicotine & Tobacco Research*, did not use the FDA’s \$10 price target as a cut off and studied cigars that, on average, sold for \$2 or more.¹¹ Premium cigars meeting the above definition are not candidates for migration or dual use, or for youth initiation or use, as recent scientific studies confirm, and therefore should be excluded from any nicotine-level standard.

Further, this definition—and, in particular, the requirement that each cigar be made by hand—effectively precludes the manufacturers of other types of cigars from rebranding their products as premium cigars. The restrictions on ingredients and the requirement of manual production together act as a significant barrier to entry. There is therefore virtually no risk that a nicotine-level standard excluding premium cigars would create a regulatory loophole and expose the public to higher risk tobacco products.

B. Premium Cigar Consumer Demographics and Patterns of Use

Premium cigars are used primarily by older, higher educated, and wealthier adults. Data from the Population Assessment of Tobacco and Health Study (the “PATH Study”), a nationally representative, longitudinal cohort study of more than 45,000 adults and youth in the United States from 2013 to 2016, provide valuable insights into the demographic profile of the typical premium cigar user. According to the *Nicotine & Tobacco Research* study, which examined PATH Wave 1 data (2013–14), 57% of adult premium cigar consumers were over the age of 35.¹² In addition, 73.8% of that group at least had completed some college or earned an associate degree (including 38.9% with a college degree or higher), and 62.7% of that group had a household income exceeding 200% of the federal poverty level—both figures considerably higher than for adult users of non-premium cigars, cigarillos, filtered cigars, and cigarettes.¹³ Another recent study in the *New England Journal of Medicine*, also using PATH Wave 1 data, found that only 2.3% of youths had *ever* used a “traditional cigar”—a category that includes both premium and non-premium cigars—and that the proportion of youth engaged in “frequent” or “daily” use of traditional cigars was so small that it was indistinguishable from zero.¹⁴

⁹ Proposed Rule, Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, 79 Fed. Reg. 23,142, 23,150 (Apr. 25, 2014).

¹⁰ Regulation of Premium Cigars, 83 Fed. Reg. 12,901 (Mar. 26, 2018).

¹¹ 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 1, supp. tbl.A (Ex. 1).

¹² *Id.* at 4 tbl.1.

¹³ *Id.*

¹⁴ Karin A. Kasza et al., *Tobacco-Product Use by Adults and Youths in the United States in 2013 and 2014*, 376 N. Eng. J. Med. 342, supp. app. tbls.S3, S4 (2017) (Ex. 2).



NERA Economic Consulting (“NERA”) has independently reviewed and analyzed the PATH data, and not only has confirmed the findings of these studies with respect to Wave 1, but also has determined that Wave 2 (2014–15) and Wave 3 (2015–16) data paint a similar demographic picture.¹⁵ NERA’s results, which will be laid out in greater detail in the Premium Cigar ANPRM Comments, indicate that approximately 57–67% of adult premium cigar consumers were over the age of 35, approximately 39–50% of adult premium cigar consumers have a college degree or higher, and approximately 65% of adult premium cigar consumers had a household income exceeding 200% of the federal poverty level (including 36–44% with household incomes exceeding \$100,000).

Premium cigars also are used very infrequently and in a manner inconsistent with use to feed nicotine addiction or otherwise as a nicotine delivery method. According to the *Nicotine & Tobacco Research* study, again analyzing PATH data, the median consumer of premium cigars used those products on 1.7 of the past 30 days and smoked 0.1 cigars per day.¹⁶ Only 6.7% of premium cigar consumers used those products daily.¹⁷ These figures stand in stark contrast to cigarettes: The median adult cigarette user smoked 29.4 days in the past month, including 10.1 cigarettes daily, and 79.5% of adult cigarette users engaged in daily use.¹⁸ NERA’s analysis underscores the infrequency of premium cigar use. Across all three PATH waves, the median adult consumer of premium cigars used those products on 1.3–1.7 of the past 30 days, and only 3.9–7.5% of adult premium cigar consumers used those products daily.¹⁹ Such low frequency of use of premium cigars simply is not consistent with using the products to satisfy a nicotine addiction or otherwise to deliver nicotine. And, as the agency observes repeatedly in the ANPRM, nicotine delivery appears to drive the frequency of tobacco use.²⁰

The data further show that premium cigar consumers are not using the products in any meaningful numbers to supplement cigarette use. In each PATH wave, the median premium cigar consumer smoked cigarettes on *zero* days in the past 30 days, compared with 29.2 days for the median filtered cigar consumer, 29.0 days for the median non-premium cigar consumer, and 19.9 days for the median cigarillo consumer (in Wave 1).²¹ Even those relatively few consumers of premium cigars who smoked cigarettes with any meaningful frequency consumed no more premium cigars than the median premium cigar user: Both used premium cigars on fewer than 2 days per month.²²

These data demonstrate that premium cigars are not being used with a frequency consistent with use as a nicotine delivery system. Rather, the data indicate that the demographics and use patterns of premium cigar consumers are dramatically different from those of consumers of other tobacco products.

¹⁵ See NERA Letter (July 16, 2018) (Ex. 3). NERA used the same definition of “premium cigar” as in the *Nicotine & Tobacco Research* study, with certain limited refinements to correct apparent misclassifications by that study’s authors. NERA’s methodology receives further elaboration in NERA’s Expert Report accompanying the Premium Cigar ANPRM Comments.

¹⁶ Corey et al., *supra* note 11, at 5 tbl.2.

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ NERA Letter at 2–3.

²⁰ See, e.g., 83 Fed. Reg. at 11,823 (“Tobacco products are addictive, primarily due to the presence of nicotine.”); *id.* at 11,824 (“The addiction potential of a nicotine delivery system varies as a function of its total nicotine dosing capability, the speed at which it can deliver nicotine, the palatability and sensory characteristics of the system, how easy it is for the user to extract nicotine, and the cost of the delivery system.”); *id.* (“The amount of nicotine delivered and the means through which it is delivered can either reduce or enhance a product’s potential for abuse and physiological effects.”); *id.* (“Quicker delivery, higher rate of absorption, and higher resulting concentration of nicotine increase the potential for addiction.”).

²¹ NERA Letter at 3.

²² *Id.* at 3–4.



Rather than as nicotine delivery devices, premium cigars are being used as luxury goods reserved for occasional indulgence primarily by older and wealthier adults. Moreover, the defining features of premium cigars—especially their all-natural and handmade character, which raise their cost—make them extraordinarily unlikely candidates for migration following the implementation of a nicotine-level standard for cigarettes. In view of these data, the FDA cannot make the statutory findings necessary to extend to premium cigars a tobacco product standard addressing nicotine levels, *see supra* Section I, and the agency should exclude premium cigars as defined in Section II.A from any such standard.

III. Premium Cigars Cannot Feasibly Comply with Any Nicotine Level Standard

In addition, a nicotine standard for premium cigars would be entirely infeasible to implement. 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 consumers seek out premium cigars for these very qualities. IPCPR 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 genetic engineering are fundamentally incompatible with the concept of a premium cigar.²³ These measures might make sense for cigarettes, which historically have been allegedly chemically engineered to maximize addictiveness and which roll off of mechanized assembly lines millions at a time, but they simply cannot be applied to natural products that have been made the same way for centuries. In short, it is not only unnecessary, but also infeasible to impose a nicotine-level standard on premium cigars.

IV. Conclusion

When announcing the FDA's new, comprehensive plan for tobacco regulation, Commissioner Gottlieb trained the agency's attention squarely on cigarettes: "The overwhelming amount of death and disease attributable to tobacco is caused by addiction to cigarettes—the only legal consumer product that, when used as intended, will kill half of all long-term users."²⁴ The agency should act consistently with Commissioner Gottlieb's vision and limit any tobacco product standard for nicotine levels to cigarettes. At the very least, the agency should exclude premium cigars from any such standard, as these luxury goods present practically no risk of tobacco initiation, migration, or dual use, and cannot, by their very nature, comply.

IPCPR appreciates the opportunity to provide comments on this important matter.

Respectfully submitted,

/s/ Scott C. Pearce

Scott C. Pearce

Executive Director

International Premium Cigar & Pipe Retailers
Association

²³ *See id.* at 11,831–32.

²⁴ Press Release, *supra* note 5.

