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RE: Comment on Proposed Emergency Regulations to Add Chapter 11, entitled "Unflavored Tobacco List," to Title 11, Division 1 of the California Code of Regulations

Comment on Proposed Unflavored Tobacco List Emergency Regulations

The Premium Cigar Association (PCA) appreciates the opportunity to comment on the California Attorney General's proposed emergency regulations currently under review by the Office of Administrative Law implementing California law that establishes the Unflavored Tobacco List (UTL).[1]

PCA represents over 250 premium cigar manufacturers, 3000 retailers, and consumers nationwide, including hundreds of small businesses in California. This comment is supported by the Boutique Cigar Association and the California Premium Cigar Association. We, along with our manufacturer and retail members, have serious concerns that these regulations, particularly the onerous fees and burdensome listing requirements, will disproportionately harm the premium cigar industry, and intrastate commerce in and around California without materially advancing public health. While we understand that these requirements do not apply to all premium cigars,

[1] See Cal. Health & Safety Code § 104559.1.

the impact of the emergency regulations as proposed would cause significant and disproportionate negative impact on manufacturers of those products otherwise qualifying as "premium cigars" under California law but sold at a wholesale cost of under $12 and would cause significant negative impact on the premium cigar industry more broadly.

We therefore urge the Department and the Office of Administrative Law to reconsider and revise the proposal in light of the following legal and economic issues.

Premium Cigars Are Unique and Not Part of the Youth Epidemic

Premium cigars are a distinct category of tobacco product with characteristics that set them apart from the mass-market products targeted by flavor bans. For these purposes, California law defines "premium cigar" as a handmade cigar (not mass produced by use of mechanization) with a whole tobacco leaf wrapper, no filter, tip, or non-tobacco mouthpiece, **and a wholesale price of at least $12**.[2] This definition reflects the high-end and unique nature of premium cigars. Similarly, the U.S. District Court for the District of Columbia recognized a definition of premium cigars in federal litigation, noting that premium cigars must, among other things, be **handmade or hand-rolled in whole tobacco leaf with at least 50 percent long filler tobacco, have no filters, contain only tobacco, water, and vegetable gum with no other ingredients or additives, and *not have any characterizing flavor other than tobacco***.[3] Notably, this definition of "premium cigar" does not set a minimum wholesale cost, recognizing that the cost of a premium cigar may vary due to numerous factors.

In other words, by their very nature premium cigars are unflavored and contain only tobacco, water, and vegetable gum adhesive. Moreover, premium cigars are luxury products used only occasionally by adults, with **no significant youth appeal or uptake**, a fact even acknowledged by the FDA, which has deemed premium cigars its *"lowest [enforcement] priority"* as compared to other tobacco products due to the minimal and infrequent youth usage.[4] Indeed, according to the National Academies of Sciences, Engineering, and Medicine, "premium cigars comprise a small share of the market compared to other cigar types. **Evidence suggests that they are less likely to be used by youth**, and most users smoke them only occasionally."[5]

There is also no evidence of rampant health-related mislabeling or adulteration in the premium cigar market. These facts underscore that premium cigars were never the primary target of California's flavored tobacco ban. However, the proposed emergency regulations would apply to

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[2] *See* Cal. Health & Safety Code § 104559.5.

[3] *See Cigar Ass'n of Am. Et al. v. U.S. Food & Drug Admin.*, Case No. 16-CV-01460 (D.D.C. Aug. 19, 2020).

[4] *See* FDA, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)*, at 31 (April 2020).

[5] National Academies of Sciences, Engineering, and Medicine. 2022. Premium Cigars: Patterns of Use, Marketing, and Health Effects. Washington, DC: The National Academies Press. https://doi.org/10.17226/26421.

all premium cigars that otherwise meet the California definition of "premium cigar" but are sold at a wholesale cost of under $12. Imposing heavy-handed regulations on products that are **already unflavored and not driving youth addiction** is unwarranted and arbitrary.

Onerous Fees and Economic Burdens on Small Businesses

The proposed emergency regulations would require every manufacturer or importer to **register each "Brand Style" of unflavored tobacco product, with a $300 initial application fee per Brand Style subject to a Product Form (or a $150 initial application fee per Brand Style subject to a Variant Form) and a $150 annual renewal fee per Brand Style thereafter**. This fee schedule, while lower than the *"up to $1,000"* per Brand Style fee authorized by statute, remains punitive. These onerous fees, particularly when viewed cumulatively over time, effectively operate as a penalty on manufacturers of unflavored tobacco products. Moreover, as to premium cigars specifically, companies typically maintain *dozens or even hundreds of distinct product lines (SKUs)* for different blends, sizes, shapes, or packaging (individual cigars, 5 packs, 10 packs, boxes), and many of these SKUs are boutique or low-volume. The definition of Brand Style renders these variations as distinct Brand Styles, each subject to the requirements for registration on the UTL. Requiring a separate fee for each Brand Style in the context of premium cigars will impose **substantial cumulative costs** that smaller manufacturers and family-owned businesses simply cannot afford. Indeed, the Department acknowledges that it anticipates a "significant share of total stock keeping units to be predicate and variant cigars that fall outside of the statute's 'Premium Cigar' classification."[6]

Industry analyses have projected that premium cigar manufacturers will incur **"millions of dollars in regulatory costs"**[7] from these fees, creating significant financial burdens. Indeed, if the proposal proceeds in its current form, **many companies have indicated they may cease offering certain cigars in California, or withdraw from the California market entirely**. This outcome would harm California's economy and consumers: local premium tobacconists will lose access to a wide variety of cigars (hurting their sales and customer satisfaction) and consumers will lose lawful product choices. In short, the fee and registration scheme, as applied to the many premium cigars sold at a wholesale cost of under $12, threatens to **stifle intrastate commerce** in a niche artisan industry without conferring meaningful public health benefits.

Due Process and Logistical Concerns

From an administrative law perspective, the emergency UTL program poses serious due process issues and logistical problems for both regulators and regulated parties. The timeline set forth is

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[6] *See* Cal. Dep't of Justice, STD 399 Attachment A, p. 1.

[7] National Academies of Sciences, Engineering, and Medicine. 2022. Premium Cigars: Patterns of Use, Marketing, and Health Effects., p. 166: "Data submitted to the committee evaluated transaction-level data from five major online cigar retailers in 2017, identifying approximately 4 million online orders in 2017 by more than 1 million unique customers across 54,554 stock keeping units (SKUs). The average number of cigar SKUs per retailer was 10,911, highlighting the diversity of products offered. The majority of these orders (3.6 million) included premium cigars: 125,314,590 sold across 51,123 SKUs."

exceedingly tight and arguably unreasonable. In order to guarantee consideration for inclusion on the UTL published by the Attorney General on or before December 1, 2025, companies will have only **45 days after the rule's finalization to prepare and submit comprehensive UTL applications for every Brand Style**. The breadth of information required by the Department as part of the necessary Product or Variant Form and the UTL Application is substantial and will require compilation of product specifications (length, ring gauge, weight, ingredients, proof of lack of flavor, etc.), design files, information on each Brand Style's regulatory status, possibly scientific analysis, and the provision of actual product samples to the Department for each Brand Style submitted through a Product Form.[8] Even with good faith efforts in making these submissions, many unflavored tobacco products otherwise eligible for listing could fail to appear on the UTL due to paperwork errors or sheer volume of submissions. Yet the consequences of not being listed are draconian: **as of January 1, 2026—potentially a mere one day following the Attorney General's publication of the UTL—any product not on the UTL is contraband subject to seizure, and retailers can be charged with civil penalties for selling tobacco products not listed on the UTL**.

Moreover, the **proposed emergency regulations do not appear to provide any grace period** for retailers to sell through inventory acquired prior to publication of the UTL. As referenced, if the Attorney General publishes the UTL on the statutory deadline of December 31, 2025, retailers could have **as little as one day** to identify and remove from shelving any products that failed to make the list.

Such an abrupt cutoff, with no sell-through period, is practicably unworkable and grossly unreasonable, especially for those specialty tobacco retailers which buy in bulk once or twice a year. Law-abiding retailers may suddenly find themselves holding thousands of dollars in unsellable stock overnight, through no fault of their own. This raises fundamental **due process and fairness concerns**, as businesses are not given reasonable notice or time to comply with the new rules. We recommend that the Department build in a more sensible transition period for retail compliance (e.g., allowing sales of unlisted tobacco products purchased by retailers prior to the date of the UTL's publication) to avoid unjust penalties and financial harm.

The proposed emergency regulations and the inevitable hurried roll-out of its implementation also fail to provide clarity on whether submissions should be made by manufacturers or importers, such that the Department may receive duplicative and potentially inconsistent submissions.

Inappropriate Standards for Determination of Inclusion on the UTL

[8] PCA also questions the purpose of requiring that the Department receive product samples for each Brand Style applying for inclusion on the UTL. PCA does not see any apparent utility in this requirement and, indeed, views this obligation as arguably further penalizing manufacturers of unflavored tobacco products.

The **presumptive "characterizing flavor" standard based on any "statement or claim" conveying that a tobacco product has a characterizing flavor** is problematic and vague. The California law being implemented by the proposed emergency regulations indicates that if a manufacturer (or any employee or agent of a manufacturer) makes any statement or claim that the tobacco product has or produces a characterizing flavor, including any **"text, color, or images"** on packaging that explicitly or implicitly suggests the presence of a characterizing flavor, the Attorney General *"shall presume"* the product to be flavored, unless the manufacturer rebuts that presumption. This could lead to arbitrary enforcement. For example, could a box label describing a cigar as "smooth" or a colored band on the label be deemed a flavor suggestion? Premium cigar branding often uses artistic designs and descriptive terms that have nothing to do with the presence of constituents that impart characterizing flavors. Yet under the proposed standard, companies might be forced to defend such products as unflavored by disclosing proprietary blend details to regulators, raising intellectual property, trade secret, and confidentiality concerns, irrespective of statutory or regulatory confidentiality protections over this information. The lack of clear criteria for what marketing triggers the presumption that a tobacco product qualifies as a "flavored tobacco product" invites subjective judgments and inconsistent outcomes, which an agency enforcing penal regulations should avoid. To comport with due process, any *"flavor"* determination ultimately must be based on whether constituents contained in the product (if any) actually cause the product to have a distinguishable taste or odor other than that of tobacco, not potentially inconsistent and arbitrary marketing interpretations. This approach would also better align with the products deemed unlawful under California law—"flavored tobacco products," which refers to tobacco products "that contain[] a *constituent* that imparts a characterizing flavor."

Further, the proposed emergency regulations would require information relating to each Brand Style exceedingly beyond the scope of information needed for the Attorney General to responsibly make a determination as to whether a tobacco product lacks a characterizing flavor. For instance, many of the product details proposed as part of the Product Form submission under Section 945 arguably have zero bearing on whether the product meets the standard for inclusion on the UTL. The Department should carefully scrutinize the categories of information demanded as part of the submission materials and limit the required information to only that required for the Department's fulfillment of its statutory obligations.

Interference with Commerce and Potential Preemption

By imposing this registry and pre-approval process for tobacco products, California is edging into a regulatory role traditionally occupied by the federal government, raising constitutional red flags. The proposed implementation of the requirement that tobacco products must appear on the UTL to be sold in California will affect not just California-based businesses, but **any out-of-state business that wishes to sell cigars to consumers in California**. For instance, an online retailer in Florida or a neighboring state that ships cigars into California could be **penalized for delivering a product not listed on the UTL**. This extraterritorial reach may implicate the

Dormant Commerce Clause, which guards against undue burdens on interstate commerce and state laws that have the practical effect of regulating commerce beyond the state's borders. Here, the compliance costs and logistical hurdles of the UTL could dissuade out-of-state cigar companies from selling to Californians at all, effectively walling off the California market. Courts will likely scrutinize whether the **burdens on interstate commerce are clearly excessive in relation to the local benefits** of the UTL program, especially given the tenuous health gains from policing premium cigars that are necessarily unflavored.

Additionally, the UTL scheme may be **preempted by federal law**. The Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act, gives the U.S. Food and Drug Administration (FDA) exclusive authority to regulate tobacco product standards and determine which products are permitted or prohibited for sale in the U.S. (through mechanisms like premarket authorization). There is a real risk that a court could view the UTL as a de facto product-approval scheme that conflicts with the FDA's authority, particularly if the state's criteria or timelines differ from federal determinations. California should ensure its regulations are narrowly focused on genuine state interests and do not function as an impermissible overlay to federal tobacco regulation.

Emergency Regulatory Status and Administrative Law

We also question the use of the **"emergency" regulatory process** for this far-reaching proposal. The Legislature's statute declared these regulations to be deemed an emergency by mandate, ostensibly to expedite implementation. However, the law prohibiting the sale of flavored tobacco products and tobacco product flavor enhancers (Senate Bill 793) was enacted in 2020, and Assembly Bill 3218 establishing the UTL was signed in 2024; thus, the issues at hand are not sudden or unforeseen. By bypassing certain normal rulemaking procedures and public input opportunities, the emergency designation risks **insufficient consideration of stakeholder concerns** (as evidenced by the significant impact on premium cigar businesses). We urge the regulators, even within the compressed timeline, to carefully consider these comments and those of other premium cigar stakeholders. The rule should not be finalized without adjustments that mitigate undue harm to lawful businesses and consumers.

Conclusion

For the reasons outlined above, PCA believes the proposed emergency regulations implementing UTL requirements, as applied to premium cigars sold at a wholesale price of under $12, are overly burdensome, legally questionable, and not aligned with their intended public health purpose. Premium cigars, unflavored and traditionally-crafted products with negligible youth usage, regardless of wholesale price, should **not be swept wholesale into an emergency regulatory scheme designed for flavored e-cigarettes and mass-market tobacco products**. We respectfully request the following actions to address our concerns:

- **Waive Fees for All Premium Cigars, Regardless of Wholesale Price:** The fee schedule should be reevaluated to avoid pricing premium cigars out of the California market. At minimum, consider imposing no fees on tobacco products that meet all definitional criteria of "premium cigar" under California law other than the minimum wholesale price, rather than annual per-Brand Style fees that accumulate to onerous sums. This would lessen the economic harm while still maintaining a list of allowable products.
- **Extend Compliance Deadlines and Grace Periods:** Provide a reasonable period (well beyond 45 days) for manufacturers to submit UTL applications, and a post-publication sell-through grace period for retailers to clear inventory of any unlisted items. This will ensure due process and prevent small businesses from being penalized due to administrative backlogs or timing issues beyond their control.
- **Clarify and Narrow the "Flavor" Presumption:** The regulations should clearly define what constitutes additives that would render a tobacco product a "flavored tobacco product" and remove vague language that could misclassify marketing descriptors as flavors. Assessment of whether a product's constituents (if any) cause the product to have a distinguishable taste or odor other than that of tobacco must serve as the basis for determining the existence of a characterizing flavor, not subjective interpretation of packaging art or wording.
- **Clarify Proper Compliance:** The regulations should specify whether product submissions are to be made by manufacturers, importers, or both. Without this clarification, the Department risks receiving duplicative or inconsistent entries for the same product, creating administrative inefficiencies and confusion for retailers and regulators. Clear assignment of responsibility will streamline compliance, reduce errors, and ensure a consistent, accurate product list.
- **Reevaluate Impacts on Interstate Commerce:** California should ensure its enforcement mechanisms do not impermissibly target out-of-state sellers or lead to effective trade barriers. In particular, we urge that California cooperate with federal authorities and defer to FDA's product authorizations (to avoid preemption issues). A state-maintained list should not become a back-door way of controlling which lawful tobacco products can be sold in California.

By incorporating these changes, the Department can still fulfill the legislative directive to enforce the flavor ban **without crushing a specialty industry** that operates responsibly and exclusively serves adult consumers. If left unmodified, the current proposal will likely face robust legal challenges and could be invalidated or delayed, to the detriment of all parties. We therefore urge a more balanced approach that truly targets the public health risks (youth-oriented flavored tobacco products) while **exempting or sparing those products, like premium cigars, regardless of wholesale price, that pose no such risk**. Thank you for considering our comments. PCA remains ready to work with California authorities on sensible regulations that protect youth without destroying legitimate adult businesses and consumer choice.