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April 30, 2019

VIA ELECTRONIC FILING (www.regulations.gov)

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Rm. 1061 (HFA-305)
Rockville, MD 20852

Re: Draft Guidance, Modifications to Compliance Policy for Certain Deemed Tobacco Products (Docket No. FDA-2019-D-0661)

Dear Sir or Madam:

The International Premium Cigar & Pipe Retailers Association ("IPCPR") appreciates the opportunity to submit these comments on the Food and Drug Administration's ("FDA's" or the "Agency's") Draft Guidance entitled "Modifications to Compliance Policy for Certain Deemed Tobacco Products" (the "Draft Guidance"). 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 members operate more than 3,500 retail stores, employ more than 20,000 people, and sell premium tobacco products including cigars and pipe tobacco. IPCPR's retail members are small businesses, typically owned and operated by families. The vast majority of our members (83%) own and operate only one store. IPCPR also has a direct economic relationship with more than 350 manufacturers, distributors, and service providers. Many of these partners are also small businesses and employ an estimated 7,000 additional people in the United States. Overall, IPCPR estimates that there are nearly 35,000 jobs tied to the premium cigar and premium tobacco retail industry in the United States.

I. Background on the Draft Guidance

On May 10, 2016, FDA issued a regulation deeming all products that meet the statutory definition of a "tobacco product," except accessories of newly deemed tobacco products, as subject to FDA's tobacco product authorities within chapter IX of the Federal Food, Drug, and Cosmetic Act (the "FFDCA").[1] The newly deemed products included the two main categories of tobacco products sold by IPCPR members: cigars and pipe tobacco.

[1] *See* 81 Fed. Reg. 28,974 (May 10, 2016).

When issuing the regulation, FDA announced a compliance policy for newly deemed products that qualify as "new tobacco products"[2] but that were on the U.S. market on the regulation's August 8, 2016, effective date ("Policy Products"). While "new tobacco products" generally require premarket authorization from FDA, the initial policy allowed the continued marketing of Policy Products until staggered deadlines for filing of marketing applications for them as well as for up to one year thereafter during FDA's review of such submissions. The deadlines ranged from August 8, 2017, to August 8, 2018, and the required date of filing depended on the type of marketing application submitted.

Subsequently, in May 2017, FDA published a guidance document entitled "Three-Month Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule." Therein, the Agency announced that FDA would extend by three months all future compliance dates for requirements for newly deemed products, including those for marketing applications for Policy Products. In July 2017, FDA announced a new comprehensive plan for tobacco product regulation intended, in part, to "ensure that the FDA has the proper scientific and regulatory foundation to efficiently and effectively implement the Family Smoking Prevention and Tobacco Control Act" and "[t]o make certain that the FDA is striking an appropriate balance between regulation and encouraging development of innovative tobacco products that may be less dangerous than cigarettes."[3] Consistent with these goals, FDA further extended the compliance dates for filing marketing applications for Policy Products to August 8, 2021, for combustible products and to August 8, 2022, for noncombustible products. FDA also revised the compliance policy by permitting the continued marketing of a Policy Product after the applicable deadline for the duration of FDA's review of a timely filed application. We will refer to the latest version of the compliance policy herein as the "Current Policy."

In the Draft Guidance, FDA proposes to modify the Current Policy in several significant ways for two categories of newly deemed products: (1) electronic nicotine delivery system ("ENDS") products; and (2) certain "flavored" cigars. FDA bases these proposed changes primarily on concerns about recent data on youth use of ENDS products. However, due to expressed concerns about possible impacts of its proposed policy for certain flavored ENDS Policy Products, FDA has also proposed to cease applying enforcement discretion for the premarket review requirements to certain "flavored" cigar Policy Products (except "tobacco flavored" products). IPCPR and its members strongly support efforts to eliminate underage access to all tobacco products. Nevertheless, we have significant concerns about the Draft Guidance's proposed modification to the Current Policy for "flavored" cigars, including especially its impacts on retailers.

II. The Draft Guidance's Proposed Policy for "Flavored" Cigars Appears Highly Unlikely to Advance FDA's Stated Goals

The Draft Guidance proposes substantial changes to the Current Policy for flavored ENDS products.[4] These include, among other things, effectively prohibiting the sale of flavored ENDS products (other than mint-, menthol-, or tobacco-flavored products): (1) in locations (or sections thereof) that permit access to minors at any time; (2) via the internet by sellers who do not verify the purchaser's age or identity using publicly available, third-party databases or who do not establish limits on the quantity of products that a purchaser can buy within a given period of time; and (3) by a retail establishment or internet seller found by FDA to have sold to a minor after the Agency issues its final version of the Draft Guidance. These changes appear intended to limit unlawful youth access to such products.

[2] *See* 21 U.S.C. § 387j(a)(1) (defining "new tobacco product" to include any product not commercially marketed in the U.S. market as of February 15, 2007, or modified in any physical respect since).
[3] https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm568923.htm.
[4] IPCPR understands that virtually all, if not all, currently marketed ENDS products qualify as "new tobacco products" and thus remain on the market today under the Current Policy.

With respect to cigars, the Draft Guidance proposes revoking FDA's Current Policy as applied to certain cigars. The Draft Guidance states, "At this time, in addition to modifying the compliance policy for ENDS products, FDA is also modifying the August 2017 Compliance Policy for "flavored" cigars. Beginning 30 days after issuance of a final guidance, FDA will prioritize enforcement of actions with respect to "flavored" cigars (other than "tobacco flavored") that were on the market on August 8, 2016, and that meet the definition of a "new tobacco product." Put differently, FDA proposes to begin enforcing the premarket review requirements against "flavored cigars (other than tobacco flavored)" that qualify as "new tobacco products" but have been marketed under the Current Policy for newly deemed products on the market on August 8, 2016. Under the Current Policy, such products may remain on the market until at least August 8, 2021, and, if the manufacturer files a marketing application for a product by that date, after that date pending FDA review of the application. In practical terms, implementation of the policy proposed in the Draft Guidance would require all such products to come off the market within 30 days to avoid enforcement action. Grandfathered "flavored" cigars (i.e., those commercially marketed in the United States as of February 15, 2007) as well as unflavored and "tobacco flavored" cigar Policy Products could remain on the market.

FDA proposes to implement its modifications to the Current Policy primarily based on concerns that minors "continue to use flavored cigars" and that implementation of the proposed modifications to the ENDS product policies could result in minors' substituting use of "flavored" cigars for flavored ENDS products that presumably they could no longer as easily access after implementation of the proposed policy modifications. Given how available data indicate that youth "flavored" cigar use remains relatively low and continues to decline, IPCPR questions the timing and basis for FDA's proposal to depart so significantly from the Current Policy, especially given how industry members have planned their businesses and regulatory compliance programs in reliance on the Current Policy and FDA's stated rationale for adopting it.

IPCPR also questions the validity of FDA's substitution concerns. In particular, it seems highly unlikely that minors who unlawfully access flavored ENDS products today could not do so still after the proposed policy modifications take effect. An overwhelming percentage of youth who use such products obtain them from so-called "social sources" (e.g., classmates, friends, and family members who lawfully purchase these products), and the Draft Guidance would do little to address such sources. Further, IPCPR finds it implausible that minors who could not unlawfully access certain flavored ENDS products as a result of the proposed policy modifications would turn to "flavored" cigars as substitutes. IPCPR bases this on the significant differences between smoking even flavored cigar tobacco and inhaling flavored aerosols emitted by ENDS devices. Further, even assuming for the sake of argument that some level of such substitution would occur, potentially thousands of grandfathered "flavored" cigars would remain on the market after implementation of the proposed policy modifications. Accordingly, revoking the Current Policy as applied to "flavored" cigars appears highly unlikely to advance FDA's stated goals.

III. The Draft Guidance's Proposed Policy for "Flavored" Cigars Is Too Vague for FDA or Industry to Implement

Should FDA nevertheless decide to proceed with implementing the "flavored" cigar policy modification proposed in the Draft Guidance, the Agency must define the term "flavored" and distinguish both unflavored products and "tobacco flavored" products from those within the scope of the policy. The Draft Guidance does not do so in any way. The lack of definitions or clarity on this issue would render the modified policy impossible to implement and enforce.

While IPCPR retailer members derive most of their revenue from sales of unflavored premium cigars, they do sell some products potentially affected by the proposed modification to the compliance policy, including most notably infused large traditional cigars. Avoiding selling products no longer subject to FDA's enforcement discretion policy would not only require retailers to distinguish between grandfathered products and products formerly subject to the Current Policy (as well cigars for which FDA may eventually issue marketing

authorizations), it would also first require distinguishing between products that FDA would consider unflavored, "tobacco flavored," and otherwise "flavored." The Draft Guidance provides no actionable criteria for manufacturers, distributors, retailers, and even FDA officials to apply for these purposes.

IPCPR notes that the FFDCA's statutory "special rule" for characterizing flavors in cigarettes and their components[5] provides at least some guidance in prohibiting natural and artificial flavors, herbs, and spices that provide a "characterizing flavor" (other than tobacco or menthol) to the product or its smoke. However, the Draft Guidance includes nothing along these lines that would facilitate meaningful compliance determinations for cigars. The following examples illustrate the challenges in applying the proposed modification to the compliance policy as applied to cigars:

- Through only tobacco cultivation, aging, and blending techniques, many cigars have unique flavor profiles that cigar marketers and smokers may describe as including "notes" of certain flavors (e.g., coffee, citrus, minerals, bittersweet chocolate). Although these products contain no additives to deliver these flavor experiences, would FDA's proposed policy modification apply to such products, or only when marketers reference such flavor notes?

- Cigar products may also contain various non-tobacco ingredients that could impact flavor but that the manufacturer uses primarily or exclusively for non-flavoring purposes (e.g., humectants, preservatives, adhesives). Would use of such ingredients render a product "flavored" for purposes of the Draft Guidance?

- Some cigar manufacturers include a variety of ingredients to impart unique flavors to their cigars, but these ingredients do not cause them to have a distinguishable characterizing aroma or flavor, such as that of a particular fruit or beverage. Would use of such ingredients render such products "flavored cigars?"

In addition, it remains quite unclear what type of product would qualify as a "tobacco flavored cigar." Would the exception apply to products with added flavoring ingredients only when such flavoring mimics the natural flavor of tobacco (or is derived from tobacco)?

Ultimately, any finalized version of the Draft Guidance would need to include much clearer lines to ensure industry understands the scope of the modification to the compliance policy and FDA can consistently apply it. In the absence of actionable definitions on this point, retailers in particular would face an impossible task in determining which products they may carry under the policy (and which they may not) given their lack of access to information on the precise manufacturing processes and ingredients used in the manufacture of cigars they sell. The lack of clarity on the scope of the proposed modification to the policy would exacerbate the additional challenge that retailers would face in attempting to distinguish between grandfathered and FDA-authorized "flavored" (other than "tobacco flavored") cigars they may sell and "flavored" (other than "tobacco flavored") cigars that, while previously marketed under the Current Policy, would need to come off the market as a result of FDA's change in approach.

IV. Industry Would Require More than 30 Days to Implement the Modifications to the Compliance Policy Proposed in the Draft Guidance

The Draft Guidance states that, 30 days after issuance of a final version of the Draft Guidance, FDA would prioritize enforcement of the premarket review requirements against non-grandfathered "flavored" cigars (other than "tobacco flavored cigars") lacking FDA marketing authorizations. The Draft Guidance does not appear to contemplate a sell-through period for non-compliant products already in the distribution system on the effective

[5] 21 U.S.C. § 387g(a)(1)(A).

date, such as that provided for the currently-stayed cigar package warning requirements at 21 C.F.R. § 1143.13(a). Given the complexities of the manufacturing, distribution, and retail system, industry would require much more time to effectively implement the modification to the compliance policy for "flavored" cigars and avoid substantial costs, confusion, losses, and inadvertent violations.

Small businesses like IPCPR's retailer members would face an especially challenging—if not impossible—task in managing their inventory to implement the policy change within 30 days. As discussed above, retailers would need to evaluate the compliance status of every potentially "flavored" cigar offered in their stores and work with suppliers to ensure the retailers have compliant inventories by the effective date. With limited resources and limited staff, including in-house regulatory compliance specialists potentially necessary for making such determinations, 30 days would prove completely inadequate.

In addition, while 30 days may suffice for some retailers to sell through inventory of affected products, IPCPR retailer members typically have much longer turnover for their cigar products than do other retailers of other tobacco products (e.g., convenience stores that sell cigarettes). Based on survey data recently released by IPCPR's sister organization, the Tobacconist Association of America, the mean premium cigar retailer takes 101.7 days to turn its inventory. Thus, on average, it takes a premium cigar retailer four times as long (101.7 days) to sell the typical premium cigar than it does the typical convenience store to sell a pack of cigarettes (24.6 days). Notably, no premium cigar retailer reported selling a premium cigar within just 30 days of receipt. While these survey results relate to premium cigars specifically, in IPCPR's experience, these data generally accord with the turnover of other cigar products carried by IPCPR retailer members, including "flavored" cigar products potentially within the scope of the Draft Guidance (e.g., infused large traditional cigars). IPCPR would therefore expect that, within 30 days of the issuance of a finalized version of the Draft Guidance, its retailer members may have substantial inventories of affected products purchased even prior to the document's issuance.

The lack of an express sell-through policy for "flavored" cigar products already in the distribution system that would lose their status under any finalized version of the Draft Guidance could also have significant financial consequences for the trade. For example, depending on the specific wholesaler or manufacturer supplier, a retailer may lack the ability to sell the products back to the supplier or otherwise receive compensation (e.g., credit) for their now-unsellable prior purchases. This could result in substantial losses to small, family-owned business, again without any demonstratable benefit to public health to justify them.

Accordingly, should FDA nevertheless decide to proceed with implementing the "flavored" cigar policy modification proposed in the Draft Guidance, IPCPR would respectfully request that FDA establish an effective date of at least 120 days after the document's publication.

V. Conclusion

IPCPR appreciates the opportunity to comment on the Draft Guidance. If you have any questions or require additional information about these comments or IPCPR, please contact me at 202-849-6042.

Sincerely yours,

Scott Pearce
Executive Director
International Premium Cigar and Pipe Retailers Association