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Via Federal eRulemaking Portal

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

Re: Modifications to Compliance Policy for Certain Deemed Tobacco Products: Draft Guidance for Industry [Docket No. FDA-2019-D-0661]

The undersigned State Attorneys General submit these comments in response to the Draft Guidance for Industry “Modifications to Compliance Policy for Certain Deemed Tobacco Products” (the “Draft Guidance”).¹

State Attorneys General have had considerable success in their long fight to protect their citizens, particularly youth, from the dangers of cigarettes. States now face a new public health scourge, however: youth use of electronic nicotine delivery systems (ENDS) including e-cigarettes.² This problem is amplified by the availability of flavored ENDS,³ their continued availability online, and the FDA’s extension of the compliance dates for their premarket authorization. The States are concerned that the Draft Guidance is inadequate to address these issues and will therefore allow the continuation of the epidemic of ENDS use among youth.

As officials of States entrusted with the power to protect the health, safety, and welfare of the public, we therefore urge the FDA to amend its Draft Guidance to: 1) include menthol and mint flavors in its enforcement priorities for ENDS; 2) advance further the compliance dates for premarket authorization for ENDS; and 3) include all online sales of ENDS in its enforcement priorities. More stringent guidance in these areas, similar to the FDA’s proposed enforcement priorities for flavored cigars, would better serve the nation’s interest in decreasing the hazards of exposure to tobacco products and in promoting the public health.

¹ Modifications to Compliance Policy for Certain Deemed Tobacco Products; Draft Guidance for Industry, *available at*: <https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM633281.pdf> [hereinafter, “Draft Guidance”].

² The FDA acknowledges that there has been a significant increase in minors’ use of ENDS products, with frequent use of ENDS products exceeding frequent use of cigarettes among high school students who are current users. Draft Guidance at 8-9.

³ The FDA acknowledges that the “[e]vidence indicates that minors are attracted to flavored ENDS products.” *Id.* at 9.

I. The FDA Should Include Menthol and Mint Flavors in its Enforcement Priorities for ENDS.

The Draft Guidance excludes menthol and mint flavored ENDS from its enforcement priorities, seemingly based on its observation that “[w]hile minors use mint and menthol ENDS products, it appears that they prefer them substantially less than adults prefer such flavors.”⁴ This statement is inconsistent with the FDA’s stated goal to target ENDS products that are “likely to promote use of ENDS by minors”—a group of products that significant evidence shows includes menthol and mint products.⁵ It also ignores the likely consequence of this exclusion—an increase in use of mint and menthol ENDS products due to the reduction in access to other flavored ENDS products.

Menthol and mint flavored ENDS products are already preferred by certain demographic groups and are likely to become more popular among those groups and others if excluded from the FDA’s enforcement priorities for ENDS. An analysis of the National Youth Tobacco Survey found that current use of menthol or mint e-cigarettes increased from 42.3% to 51.2% among all current e-cigarette using high school students during 2017-2018.⁶ Similarly, a study in New York also confirmed the popularity of menthol and mint flavors with youth: nearly half of adolescent e-cigarette users surveyed reported liking fruit flavors the best, followed by menthol or mint, and a combined category of chocolate, candy, or other sweets.⁷ Moreover, evidence also shows that menthol in e-cigarettes may put both youth and African Americans at risk for greater rates of e-cigarette initiation and use.⁸ If other flavors of ENDS are suddenly unavailable, these groups are even more likely to begin using menthol and mint flavors. As the FDA admits in the Draft Guidance, “[h]istorical evidence suggests that flavored tobacco product users might be willing to move to other flavored tobacco products if their preferred product is no longer available.”⁹

⁴ Draft Guidance at 10; *see also id.* at 19.

⁵ Compare Draft Guidance at 13, 15 (stating the FDA’s enforcement priorities), and Draft Guidance at 9 (“Evidence indicates that minors are attracted to flavored ENDS products.”). *See also* S. Zare, et al., *A systematic review of consumer preference for e-cigarette attributes: Flavor, nicotine strength, and type*, 13 PLoS ONE 2018 1, 8 (2018) (Supp. 3) (“[A]dolescents (mostly non-smokers) were more likely to try e-cigarettes with candy, fruit, and menthol flavors than tobacco or alcohol flavors.”).

⁶ Cullen KA, Ambrose BK, Gentzke AS, Apelberg BJ, Jamal A, King BA. Notes from the Field: Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students — United States, 2011–2018. *MMWR Morb Mortal Wkly Rep* 2018;67:1276–1277. DOI: <http://dx.doi.org/10.15585/mmwr.mm6745a5> (Among high school students during 2017-2018, current use of menthol or mint e-cigarettes increased among all current e-cigarette users from 42.3% to 51.2% and among current exclusive e-cigarette users from 21.4% to 38.1%.

⁷ A. Henes, et al., *2017 Adolescent E-Cigarette Survey*, RTI INT’L (2017) (unpublished data).

⁸ Hyoshin Kim, et al. *Role of Sweet and Other Flavours in Liking and Disliking of Electronic Cigarettes*, 25 TOBACCO CONTROL 1, 5 (2016) (Supp. 2). *See generally* Kim Klausner, *Menthol Cigarettes and Smoking Initiation: A Tobacco Industry Perspective*, 20 TOBACCO CONTROL 12 (2011) (Supp. 2) (summarizing tobacco industry efforts to target menthol to African American communities).

⁹ Draft Guidance at 17.

Risking this shift of youth from one flavor of ENDS to another is not justified by any potential but indeterminate impact on adult smokers. As noted by the Surgeon General’s 2016 report on e-cigarettes, “the evidence supporting the effectiveness of e-cigarettes as an aid for quitting conventional cigarettes remains extremely weak for adults and untested and nonexistent among youth.”¹⁰ The evidence that flavored e-cigarettes assist in quitting smoking is similarly inconclusive.¹¹

II. The FDA Should Advance the Compliance Date for Premarket Authorization for ENDS.

The Draft Guidance sets the deadline for manufacturers to submit premarket applications for flavored ENDS products (other than those flavored with tobacco, mint, or menthol) as August 8, 2021—a full three years after the last deadline set in the FDA’s 2016 Final Deeming Rule.¹² The States appreciate that this is one year sooner than the deadline FDA proposed in its 2017 guidance¹³ but still believe that it is inadequate for the protection of the nation’s public health, especially since, like in the 2017 guidance, the FDA also proposes to continue deferring enforcement with respect to those products for which an application has been submitted until it renders a decision on the application.¹⁴

Given the mounting evidence of an “epidemic of youth e-cigarette use,”¹⁵ the FDA should advance the deadline for manufacturers to submit premarket applications for all ENDS products to August 8, 2020 at the latest. Like it proposed in the Deeming Rule, the FDA should also begin enforcement with respect to those products for which an application has been submitted but an agency decision has not been made twelve months after August 8, 2020. Enforcement beginning at a date certain regardless of agency decision on a particular application will almost certainly incentivize submission of complete and accurate applications as soon as possible. This accords with the FDA’s stated goal to prompt manufacturers to “move up their filing of premarket submission for certain deemed tobacco products.”¹⁶

¹⁰ U.S. DEP’T. OF HEALTH & HUMAN SERVS., E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL, 124 (2016), https://e-cigarettes.surgeongeneral.gov/documents/2016_sgr_full_report_non-508.pdf.

¹¹ S. Zare, et al., *A systematic review of consumer preference for e-cigarette attributes: Flavor, nicotine strength, and type*, 13 PLoS ONE 2018 (2018) (Supp. 3).

¹² Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28973 (2016).

¹³ See Draft Guidance at 4 (detailing the August 2017 Compliance Policy).

¹⁴ See *id.* at 4, 13-14.

¹⁵ Surgeon General’s Advisory on E-Cigarette Use Among Youth (Dec. 18, 2018), <https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf>.

¹⁶ Draft Guidance at 6.

This is particularly important given other recent safety concerns regarding ENDS. On April 3, 2019, the FDA announced that it “has become aware that some users who use e-cigarettes have experienced seizures, with most reports involving youth or young adult users.”¹⁷ There is also a growing body of literature concluding that the flavorants in tobacco products are in and of themselves unsafe.¹⁸ Given the scientific uncertainty surrounding these serious issues, the FDA should advance the compliance date for premarket authorization for ENDS and reinstitute a defined grace period after filing.

III. The FDA Should Ban Online Sales of ENDS.

Despite its acknowledgement that minors utilize online retailers to obtain ENDS, the FDA seeks to prioritize enforcement against only certain online sales—those without a quantity limit and those without independent age and identity verification.¹⁹ This prioritization is unlikely to be effective at preventing all sales of ENDS to minors, and the FDA should therefore ban all online sales of ENDS instead.²⁰ Additionally, this prioritization is inadequate to address another effect of online sales of tobacco products – *i.e.*, making such products less expensive through evasion of state taxes, which makes them more readily available to youth.

¹⁷ Press Release, U.S. Food & Drug Admin., Some E-cigarette Users Are Having Seizures, Most Reports Involving Youth and Young Adults (Apr. 3, 2019), <https://www.fda.gov/TobaccoProducts/NewsEvents/ucm635133.htm>.

¹⁸ See, e.g., Esther E. Omaiye, et al., *High concentrations of flavor chemicals are present in electronic cigarette refill fluids*, SCIENTIFIC REPORTS 9:2468 (2019) (finding flavor chemicals at cytotoxic levels in commercially available e-liquids); Hae-Ryung Park, et al., *Transcriptomic response of primary human airway epithelial cells to flavoring chemicals in electronic cigarettes*, SCIENTIFIC REPORTS 9:1400 (2019) (find that the commonly used ENDS flavorants diacetyl and 2,3-pentanedione were linked with changes in gene expression that could impair both the production and function of cilia in the airway epithelium); Jessica L. Fetterman et al., *Flavorings in Tobacco Products Induce Endothelial Cell Dysfunction*, 38 ARTERIOSCLEROSIS, THROMBOSIS, & VASCULAR BIOLOGY 1607, 1610 (2018) (finding that exposure to certain flavorants induced both inflammation and impaired A23187-stimulated nitric oxide production); see generally M. Flori Sassano et al., *Evaluation Of E-Liquid Toxicity Using an Open-Source High-Throughput Screening Assay* 16 PLOS BIOLOGY 1 (2018) (measuring toxicity of flavorants found in commercially available e-liquids); Mark L. Rubinstein, Kevin Delucchi, Neal L. Benowitz, & Danielle E. Ramo, *Adolescent Exposure to Toxic Volatile Organic Chemicals From E-Cigarettes*, 141 PEDIATRICS 1, 7 (2018) (finding that urine of teenagers who used fruit-flavored e-cigarettes had significantly higher levels of the metabolites of acrylonitrile, a highly poisonous compound used widely in the manufacture of plastics, adhesives, and synthetic rubber).

¹⁹ Draft Guidance at 11, 13.

²⁰ The Prevent All Cigarette Trafficking Act (the “PACT Act”), enacted in March 2010, does address the sale and distribution of cigarettes and smokeless tobacco via the Internet, e-mail, telephone, direct mail and other non-face-to-face means, but it does not apply to other categories of tobacco products.

IV. The FDA Is Correct to Prioritize Enforcement of Actions With Respect to Flavored Cigars, Including Menthol and Mint Flavored Cigars.

As noted in the Draft Guidance,²¹ flavored cigars proliferated in the marketplace in the wake of the prohibition on flavored cigarettes contained in the Tobacco Control Act (the “TCA”).²² Young adult cigar smokers in particular have a clear preference for flavored cigars.²³ In 2010-11, youth, young adults, and African Americans were “significantly more likely” to report a usual cigar brand that was flavored.²⁴ While the States appreciate the FDA’s effort in recognizing that decreased availability of flavored ENDS products would likely have a similar result of migration to flavored cigars, the States believe that more enforcement action with regard to flavored cigars is necessary. The States therefore support the FDA’s proposed policy of applying premarket authorization requirements to flavored cigars and encourage the FDA to take stronger enforcement action regarding flavored cigars.

Prioritizing enforcement of actions with respect to flavored cigars would help close a large loophole in the TCA’s implementation and more fully achieve the public health goals of its prohibition on flavored cigarettes. Recent studies have shown that banning flavors in tobacco products has led to increased quit attempts overall, as well as declining tobacco use among teens—clear public health benefits.²⁵ For example, in a 2017 study analyzing the effect of New York City’s ban on flavored cigars, cigarillos, little cigars, chew, snuff, snus, tobacco, pipe tobacco, roll-your-own tobacco, and dissolvables (as measured by retail tobacco sales), the researchers found that sales of those products, as well as the odds of ever using such products, declined significantly among teens after the flavor ban went into effect.²⁶ Moreover, following enforcement of New

²¹ Draft Guidance at 17.

²² See, e.g., OFFICE OF THE SURGEON GENERAL, U.S. DEP’T OF HEALTH & HUMAN SERVS., PREVENTING TOBACCO USE AMONG YOUTH AND YOUNG ADULTS 205 (2012) (“Djarum clove cigarettes reemerged in the market as clove flavored cigars, and Sweet Dreams flavored cigarettes re-emerged as Sweet Dreams flavored cigars.” (citation omitted)).

²³ Adrienne S. Viola et al., *A Cigar by Any Other Name Would Taste as Sweet*, 25 TOBACCO CONTROL, 605, 606 (2016). In fact, cigars are the most popular tobacco product among African American youth, and young adult cigar smokers have a clear preference for flavored cigars. *Id.*

²³ Regulation of Flavors in Tobacco Products, 83 Fed. Reg. 12294, 12297 (Mar. 21, 2018).

²⁴ Ganna Kostygina, Stanton A. Glantz, & Pamela M. Ling, *Tobacco Industry Use of Flavours to Recruit New Users of Little Cigars and Cigarillos*, 25 TOBACCO CONTROL 66 (2016).

²⁵ See, e.g., S.M. Farley & M. Johns, *New York City Flavoured Tobacco Product Sales Ban Evaluation*, 26 TOBACCO CONTROL, 78 (2017) (describing the decline of sales of flavoured tobacco, cigars, and pipes); Ontario Tobacco Research Unit, *Evaluation of Ontario’s Menthol Ban* (Mar. 2018), https://otru.org/wp-content/uploads/2018/03/update_march2018a.pdf.

²⁶ S.M. Farley & M. Johns, *New York City Flavoured Tobacco Product Sales Ban Evaluation*, 26 TOBACCO CONTROL, 78 (2017). The New York City ban excludes menthol. *Id.*

York City’s flavor ban, teens had lower odds of using *any* type of tobacco product, including those that are not flavored.²⁷

Additionally, the States urge the FDA to take concrete actions in prioritizing enforcement of actions with respect to flavored cigars, including removal from the marketplace. The States note, by way of comparison, that the FDA sent four letters to little cigar manufacturers in December 2016, warning them that they were violating the TCA by “selling flavored cigarettes that are labeled as little cigars or cigars.”²⁸ Despite the letters, two of the recipients still display the offending products on their websites,²⁹ and though the other two websites are now hidden behind login pages, the other two products similarly appear to be still available for sale.³⁰ Stronger enforcement action is necessary for flavored cigar products that have not received premarket authorization in order for the revised guidance to realize its goal of preventing “minors who use flavored ENDS products [from] migrat[ing] to flavored cigars after th[e] guidance is finalized.”³¹

V. Conclusion

In light of the above and the potential effects on the health, safety, and welfare of the States’ residents, the States urge the FDA to amend its Draft Guidance to: 1) include menthol and mint flavors in its enforcement priorities for ENDS; 2) advance the compliance date for premarket authorization for ENDS; and 3) include all online sales of ENDS in its enforcement priorities. More stringent guidance in these areas, as well as concrete actions in prioritizing enforcement of actions with respect to flavored cigars, will benefit the public health in far greater ways than those

²⁷ *Id.*

²⁸ Press Release, U.S. Food & Drug Admin., FDA Takes Action Against Four Tobacco Manufacturers (Dec. 9, 2016), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm532563.htm>.

²⁹ *Compare Filtered Cigars*, SWISHER.COM, <https://swisher.com/filtered-cigars/?product=swisher-sweets> (last visited Mar. 21, 2019) (displaying Swisher Sweets Grape “little cigars”), and *Criss-Cross Cigars*, SXBRANDS.COM, https://www.sxbrands.com/products/criss_cross_cigars (last visited Mar. 21, 2019) (displaying Criss-Cross 100’s Cherry “filtered cigars”), with Letter from Ann Simoneau, Director, Office of Compliance & Enforcement, Ctr. for Tobacco Prods., U.S. Food & Drug Admin., to Peter Ghiloni, President, Swisher Int’l, Inc. (Dec. 9, 2016), <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm532254.htm>, and Letter from Ann Simoneau, Director, Office of Compliance & Enforcement, Ctr. for Tobacco Prods., U.S. Food & Drug Admin., to Richard L. Prezelski, President, S. Cross Tobacco Co., Inc. (Dec. 9, 2016), <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm532265.htm>.

³⁰ *Compare Cheyenne Filtered Cigars Wild Cherry*, JRCIGARS.COM, <https://www.jrcigars.com/item/cheyenne-filtered-cigars/wild-cherry> (last visited Mar. 21, 2019) (displaying Cheyenne 100’s Wild Cherry “cigars” for sale), and *Prime Time Little Cigars Strawberry*, CHEAPLITTLECIGARS.COM, https://www.cheaplittlecigars.com/Prime-Time-Little-Cigars-Strawberry_p_2302.html (last visited Mar. 21, 2019) (displaying Prime Time Strawberry “little cigars” for sale), with Letter from Ann Simoneau, Director, Office of Compliance & Enforcement, Ctr. for Tobacco Prods., U.S. Food & Drug Admin., to David A. Scott, Chief Exec. Officer, Cheyenne Int’l, LLC (Dec. 9, 2016), <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm532249.htm>, and Letter from Ann Simoneau, Director, Office of Compliance & Enforcement, Ctr. for Tobacco Prods., U.S. Food & Drug Admin., to James L. Emery, Chief Exec. Officer, Prime Time Int’l Distrib., Inc. (Dec. 9, 2016), <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm532259.htm>.

³¹ Draft Guidance at 16.

proposed in the Draft Guidance, and the States urge the FDA to adopt them.

Respectfully submitted,



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