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TO: NACS

FROM: Doug Kantor

RE: The FDA's Draft Guidance on Certain Deemed Tobacco Products

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On March 13, 2019, the Food and Drug Administration (FDA) released draft guidance[1] that would change the state of the law for certain deemed tobacco products that have not received premarket authorization. FDA has promoted these changes as a way to make it more difficult for kids to access flavored electronic nicotine delivery systems (ENDS), such as e-cigarettes.

The draft guidance proposes the following changes to FDA's tobacco policy:

1. **Revokes the Pre-Market Approval Delay for Flavored ENDS Products**

In August 2017, the FDA issued a compliance policy for ENDS products. That policy delayed – until 2021 – the requirement that ENDS products go through the premarket approval process as required in the Family Smoking Prevention and Tobacco Control Act.

The draft guidance would revoke the delay for the pre-market approval requirement for ENDS products that are flavored with any flavor except tobacco, mint, and menthol, beginning 30 days after the guidance is finalized. Because no ENDS products have gone through the pre-market approval process, this change in policy will make the designated flavored ENDS products illegal to sell until such time as those products receive approval from the FDA. Because FDA has concerns about these products, there are questions as to whether these flavored ENDS products will receive premarket approval at a future date.

2. **Allow Some Retailers to Sell Flavored ENDS by Focusing Enforcement Elsewhere**

As described in the draft guidance, FDA is prioritizing the enforcement of its new policy so that some retail outlets will not be able to sell flavored ENDS products while others will be able to do so. To that end, FDA will prioritize enforcement against locations that allow underage people to enter the store, like convenience stores. FDA will also enforce against online retailers that do not limit the amount of flavored ENDS products that can be sold during a "given period of time" and online retailers that do not verify identity and ages against third-party data.

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[1] Department of Health and Human Services, Food and Drug Administration, *Modifications to Compliance Policy for Certain Deemed Tobacco Products: Guidance for Industry* (March 13, 2019); *available at* https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM633281.pdf.

By outlining its enforcement priorities, FDA is signaling to adult-only establishments (such as smoke shops and vape shops) and online retailers that limit sales amounts and verify age against a database that the Agency will not enforce its new policy against them. By describing the specific instances of online retailer enforcement, FDA appears to be saying that many online retailers will be able to sell flavored ENDS products even though those products have not received pre-market approval. And, the draft guidance effectively bans the designated flavors of product in stores that allow underage patrons to enter.

FDA further explains that after August 8, 2021, the Agency will prioritize enforcement against manufacturers that have not submitted a premarket application.

3. Stops Marketing of ENDS Products to Kids

FDA has requested that stakeholders submit examples of products that are marketed to minors, such as those that use cartoons or "resemble kid-friendly foods." FDA will also prioritize enforcement against the sale of these products.

4. Bans on Flavors in Cigars

FDA is also proposing to modify its compliance policy for flavored cigars. FDA plans to prioritize enforcement against all cigars that are flavored (other than tobacco flavored), were on the market as of August 8, 2016, and "meet the definition of a new tobacco product," meaning they entered the market as after February 15, 2007. As part of their efforts, FDA will prioritize enforcement on mint- and menthol-flavored cigars, even though mint- and menthol-flavored ENDS products remain legal at this time.

Furthermore, FDA is seeking data on flavored cigars that were on the market as of February 15, 2007. FDA's request for information could likely inform a future rulemaking that would ban flavors in all cigars, even those on the market before February 15, 2007.

5. Future FDA Actions

FDA warned that it is considering additional changes in policy for waterpipe tobacco, or hookah, products. FDA also cautioned that it could decide to revise the compliance policy of mint- and menthol-flavored ENDS products at a later date if there is an increase in uptake by underage users. At this time, however, FDA is not reviewing its policies for pipe tobacco and dissolvable tobacco products.

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Comments on the draft guidance are due on April 15, 2019. NACS will submit comments and we encourage NACS members to do the same. Please do not hesitate to contact us if you have any questions.