

FDA should finalize the proposed rule prohibiting characterizing flavors in cigars and make it effective 90 days after publication of the final rule

**Docket No. FDA-2021-N-1309
for “Tobacco Product Standard for Characterizing Flavors in Cigars”**

Wendy Max, PhD; Lauren Kass Lempert, JD, MPH; Stanton A. Glantz, PhD; Hai-Yen Sung, PhD; Yingning Wang, PhD; Justin S. White, PhD; Bonnie Halpern-Felsher, PhD; Benjamin W. Chaffee, DDS MPH PhD; Leila Mohammadi, MD, PhD; Vira Pravosud, MS, MPH, PhD; Kristin Hoeft, PhD, MPH; Pamela M. Ling, MD, MPH

UCSF TCORS

June 15, 2022

The Food and Drug Administration’s proposed rule to prohibit characterizing flavors in cigars will reduce youth and young adult initiation rates of smoking cigars and significantly reduce premature deaths and illnesses related to tobacco use. Youth and young adults are especially attracted to the flavors in cigars, increasing the likelihood that they will initiate and progress to regular cigar smoking, and perhaps continue smoking other tobacco products concurrently with cigars. Moreover, the proposed rule correctly states that youth and young adults, racial minorities, those with low-income, and LGBTQ populations use cigars at disproportionately higher rates which contributes to health disparities. By removing flavors from cigars, FDA will take an important step towards reducing the appeal of these products and addressing tobacco-related deaths and health disparities.

We generally support FDA’s proposed rule which is based on good science. *Because of the tremendous health impacts that would accrue from the enactment of this proposed standard, we urge FDA to finalize the proposed rule and make it effective 90 days after the date of publication of the final rule.*

As FDA correctly stated, any additional delays “would only increase the numbers of youth and young adults who experiment with and become regular smokers after experimenting with flavored cigars, would delay cessation by current smokers, and would exacerbate tobacco-related health disparities.”¹

1. Every month delay in implementing the proposed flavor standard would result in an additional 44,000 new cigar smokers

Based on data from the 2019 National Survey on Drug Use and Health,² FDA determined that every day 1,210 youth (aged 12-17) and 3,163 young adults (aged 18-25) smoke their first

¹ US Food and Drug Administration, Tobacco Product Standard for Characterizing Flavors in Cigars, May 4, 2022, Proposed Rule, 87 FR 26396 at 26438.

² Substance Abuse and Mental Health Services Administration. “Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health (HHS Publication No. PEP20-

cigar.³ And Wave 5 PATH data⁴ show that for 60.4% of youth and 63.2% of young adults, this first cigar is flavored.⁵ This means that 731 youth and 1,999 young adults smoke a first cigar that is flavored each day, and each month, 12,925 youth and 59,970 young adults (81,895 youth and young adults combined) smoke a first flavored cigar.

FDA accurately reports that many studies indicate that “experimentation with cigars is associated with progression to regular use, the majority of youth and young adults who initiate cigar use do so with flavored cigars, and initiating with flavored cigars (compared to non-flavored cigars) is associated with an increased risk of current and ongoing tobacco use, as compared to experimentation with non-flavored cigars. To the extent that youth and young adult cigar users using a flavored cigar on their first use would not otherwise initiate with non-flavored cigars or other tobacco products, the proposed standard would prevent future tobacco-related disease and death among these youth and young adults.”⁶ FDA concluded that prohibiting characterizing flavors in cigars “would reduce the likelihood that youth and young adults would initiate cigar use and also mean fewer youth and young adults progressing to regular cigar use.”⁷

If cigar smokers behave similarly to cigarette smokers, 54% of youth and young adults would not start smoking cigars.⁸ ***Thus, every month delay in implementing the ban would result in an additional 44,000 new cigar smokers.***

2. FDA must not delay implementing the proposed flavor standard for one year because each year of delay causes an additional 774 premature deaths

FDA’s own statistical analysis estimated that 774 deaths (equal to 15% of the 5,200 annual deaths from exclusive cigar smoking) would be averted annually by implementing the prohibition of flavors in cigars.⁹ Based on FDA’s analysis, which may underestimate the likely benefits, ***each month of delay would cause an additional 65 deaths, and even a 90-day (three-month) implementation period would lead to 195 avoidable, premature deaths.***

To protect public health and avoid preventable premature deaths, FDA must not delay a single additional day.

07-01-001, NSDUH Series H-55).” Rockville, MD: Center for Behavioral Health Statistics and Quality, 2020. Available at <https://nsduhweb.rti.org/respweb/homepage.cfm>

³ US Food and Drug Administration, Tobacco Product Standard for Characterizing Flavors in Cigars, May 4, 2022, Proposed Rule, 87 FR 26396 at 26406.

⁴ FDA, “Memorandum of Summary of Internal Analyses of Flavored Cigars Using Wave 5 of the Population Assessment of Tobacco and Health (PATH) Study.” Silver Spring, MD: HHS, FDA, Center for Tobacco Products, 2021.

⁵ US Food and Drug Administration, Tobacco Product Standard for Characterizing Flavors in Cigars, May 4, 2022, Proposed Rule, 87 FR 26396 at 26404.

⁶ US Food and Drug Administration, Tobacco Product Standard for Characterizing Flavors in Cigars, May 4, 2022, Proposed Rule, 87 FR 26396 at 26425.

⁷ US Food and Drug Administration, Tobacco Product Standard for Characterizing Flavors in Cigars, May 4, 2022, Proposed Rule, 87 FR 26396 at 26426.

⁸ Harrell MB, Loukas A, Jackson CD, Marti CN, Perry CL. Flavored tobacco product use among youth and young adults: What if flavors didn't exist?. *Tobacco regulatory science*. 2017 Apr 1;3(2):168-73.

⁹ US Food and Drug Administration, Tobacco Product Standard for Characterizing Flavors in Cigars, May 4, 2022, Proposed Rule, 87 FR 26396 at 26430-26431.

3. To protect public health and save lives, FDA should set the effective date for the proposed standard 90 days after publication of the final rule

FDA noted that the Family Smoking Prevention and Tobacco Control Act banned all characterizing flavors (except menthol) in cigarettes with a 90-day effective date, however it proposed a longer effective date of one year in the proposed standard prohibiting characterizing flavors in cigars.¹⁰ Tobacco Control Act section 907(d)(2) provides that product standards should take effect at least one year after the date of its publication “*unless the Secretary [FDA] determines that an earlier effective date is necessary for the protection of the public health.*” FDA requested comments as to whether a shorter effective date (such as 90 days) would be necessary for the protection of the public health.

An earlier effective date is necessary to protect the public health. As explained above, FDA’s analyses found that every month of delay in implementing the proposed standard translates to 44,000 new cigar smokers and an additional 65 premature deaths. This means that ***shortening the effective date by nine months (from one-year to 90-days) would prevent an additional 396,000 people from initiating cigar smoking and would prevent an additional 585 premature deaths.***

Tobacco companies successfully removed flavored cigarettes from store shelves within 90 days of implementation of the 2009 Tobacco Control Act, so they can certainly remove flavored cigars from market shelves within 90 days.

There is no justification for extending the period beyond what was necessary in 2009, and 396,000 reasons to shorten the time.

4. The tobacco industry has had more than enough time to prepare for the proposed flavor standard as they have had ample notice and have been researching and lobbying against a flavor standard for at least 13 years.

In the preamble to the proposed rule, the FDA lays out in detail the background and relevant regulatory history of the proposed standard that would prohibit characterizing flavors in cigars.¹¹ The industry has known since long before the Tobacco Control Act was enacted in June 2009 that FDA was considering prohibiting characterizing flavors in tobacco products and has strenuously worked to oppose this outcome. In 2018 FDA issued an Advanced Notice of Proposed Rule Making (ANPRM) related to characterizing flavors in tobacco products, including in cigars, giving the industry and other interested parties adequate time to prepare.

5. Conclusion

The industry’s efforts to further delay this life-saving standard are motivated by a desire to protect their bottom line and increase profits; in contrast, the FDA’s mandate is to protect the

¹⁰ US Food and Drug Administration, Tobacco Product Standard for Characterizing Flavors in Cigars, May 4, 2022, Proposed Rule, 87 FR 26396 at 26438.

¹¹ US Food and Drug Administration, Tobacco Product Standard for Characterizing Flavors in Cigars, May 4, 2022, Proposed Rule, 87 FR 26396 at 26399-26402.

public health and reduce smoking-attributable deaths and disease. Therefore, we urge FDA to finalize the rule and make it effective 90 days after publication of the final rule.