

CTP should finalize the proposed rules prohibiting menthol in cigarettes and prohibiting characterizing flavors in cigars, and the rules should include menthol analogs with cooling agents that mimic menthol

**Docket No. FDA–2023–N–2873
Developing FDA’s Center for Tobacco Products’ Strategic Plan**

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FDA announced¹ a Public Meeting and Listening Session and an opportunity to submit written public comments to obtain feedback on five proposed strategic goals it is using to develop a strategic plan for FDA’s Center for Tobacco Products’ (CTP) comprehensive Strategic Plan. CTP proposed four cross-cutting themes – (1) health equity; (2) science; (3) transparency; and (4) stakeholder engagement – in proposing the following five goals:

1. Develop, advance, and communicate comprehensive and impactful tobacco regulations and guidance;
2. Ensure timely, clear, and consistent product application review to protect public health;
3. Ensure compliance of regulated industry and tobacco products utilizing all available tools, including robust enforcement actions;
4. Improve public health by enhancing knowledge and understanding of CTP tobacco product regulation and the risks associated with tobacco product use; and
5. Advance operational excellence.

This comment addresses the first goal and urges CTP to finalize the rules it proposed in April 2022 that would set product standards prohibiting menthol in cigarettes and flavors in cigars. It emphasizes how these proposed product standards will advance health equity and are based on valid scientific evidence. CTP promised it would finalize these rules by December 2023 and it should meet its self-imposed deadline.

¹ US Food and Drug Administration, CTP Newsroom, Listening Session: Developing FDA’s Center for Tobacco Products’ Strategic Plan, August 22, 2023 (July 21, 2023). Available: https://www.fda.gov/tobacco-products/ctp-newsroom/listening-session-developing-fdas-center-tobacco-products-strategic-plan-08222023?utm_campaign=ctp-ruf&utm_content=landingpage&utm_medium=email&utm_source=govdelivery&utm_term=stratcomms#Proposed%20Strategic%20Goals

1. CTP should finalize the proposed rules prohibiting menthol in cigarettes and prohibiting characterizing flavors in cigars

- In April 2022, FDA announced² proposed product standards to prohibit menthol as a characterizing flavor in cigarettes³ and to prohibit all characterizing flavors in cigars.⁴
- As FDA stated in the preamble to the proposed menthol rule, the proposed product standard would reduce the appeal of cigarettes, particularly to youth and young adults, and thereby decrease the likelihood that nonusers who would otherwise experiment with menthol cigarettes would progress to regular smoking.
- Importantly, the proposed standard would reduce tobacco-related health disparities and advance health equity. As we discussed in a public comment UCSF and colleagues submitted to the proposed menthol standard docket in June 2022, menthol has caused disproportionate health impacts to the African American community compared with the total toll in the US and the proposed standard would substantially decrease these harms and inequities.⁵

² FDA News Release, FDA Proposes Rules Prohibiting Menthol Cigarettes and Flavored Cigars to Prevent Youth Initiation, Significantly Reduce Tobacco-Related Disease and Death, April 28, 2022. Available: <https://www.fda.gov/news-events/press-announcements/fda-proposes-rules-prohibiting-menthol-cigarettes-and-flavored-cigars-prevent-youth-initiation>

³ US Food and Drug Administration, Tobacco Product Standard for Menthol in Cigarettes, Proposed Rule, 87 FR 26454. Available: https://www.federalregister.gov/documents/2022/05/04/2022-08994/tobacco-product-standard-for-menthol-in-cigarettes?utm_medium=email&utm_source=govdelivery

⁴ US Food and Drug Administration, Tobacco Product Standard for Characterizing Flavors in Cigars Proposed Rule, 87 FR 26396. Available: https://www.federalregister.gov/documents/2022/05/04/2022-08993/tobacco-product-standard-for-characterizing-flavors-in-cigars?utm_medium=email&utm_source=govdelivery

⁵ Valerie Yerger, Carol McGruder, Phillip Gardiner, David Mendez et al. As a matter of health equity and social justice, FDA should immediately finalize and implement the proposed standard for menthol in cigarettes to reduce smoking-attributable deaths and health disparities among African Americans, Docket No. FDA-2021-N-1349 June 24, 2022. Available: <https://www.regulations.gov/comment/FDA-2021-N-1349-114026>

- In addition, the proposed tobacco product standard would improve the health and reduce the mortality risk of current menthol cigarette smokers by decreasing cigarette consumption and increasing the likelihood of cessation.^{6, 7, 8, 9, 10, 11, 12}
- UCSF submitted eight public comments in June 2022 supporting the proposed standards prohibiting menthol in cigarettes¹³ and five comments supporting the proposed standard prohibiting characterizing flavors in cigars,¹⁴ which we incorporate by reference.

⁶ Yerger V. What more evidence is needed? Remove menthol cigarettes from the marketplace-now. *Tob Control*. 2022 Jul;31(4):493-494. doi: 10.1136/tobaccocontrol-2021-056988. Epub 2021 Sep 16. PMID: 34535506.

⁷ Vijayaraghavan M, King BA. Advancing Housing and Health: Promoting Smoking Cessation in Permanent Supportive Housing. *Public Health Rep*. 2020 Jul/Aug;135(4):415-419. doi: 10.1177/0033354920922374. Epub 2020 Apr 30. PMID: 32353245; PMCID: PMC7383751.

⁸ Brown T, Platt S, Amos A. Equity impact of population-level interventions and policies to reduce smoking in adults: a systematic review. *Drug Alcohol Depend*. 2014 May 1;138:7-16. doi: 10.1016/j.drugalcdep.2014.03.001. Epub 2014 Mar 13. PMID: 24674707.

⁹ Lee JGL, DeMarco ME, Beymer MR, Shover CL, Bolan RK. Tobacco-Free Policies and Tobacco Cessation Systems at Health Centers Serving Lesbian, Gay, Bisexual, and Transgender Clients. *LGBT Health*. 2018 May/Jun;5(4):264-269. doi: 10.1089/lgbt.2017.0208. Epub 2018 Apr 16. PMID: 29658846; PMCID: PMC6913102.

¹⁰ Guydish J, Wahleithner J, Williams D, Yip D. Tobacco-free grounds implementation in California residential substance use disorder (SUD) treatment programs. *J Addict Dis*. 2020 Jan-Mar;38(1):55-63. doi: 10.1080/10550887.2020.1713687. Epub 2020 Jan 25. PMID: 32186480.

¹¹ Fong GT, Chung-Hall J, Meng G, Craig LV, Thompson ME, Quah ACK, Cummings KM, Hyland A, O'Connor RJ, Levy DT, Delnevo CD, Ganz O, Eissenberg T, Soule EK, Schwartz R, Cohen JE, Chaiton MO. Impact of Canada's menthol cigarette ban on quitting among menthol smokers: pooled analysis of pre-post evaluation from the ITC Project and the Ontario Menthol Ban Study and projections of impact in the USA. *Tob Control*. 2022 Apr 28;tobaccocontrol-2021-057227.

¹² Maya Vijayaraghavan, Pamela Ling, Valerie Yerger, et al. UCSF Public Comment regarding HHS 2023 Framework to Support and Accelerate Smoking Cessation, July 29, 2023. Available: <https://tobacco.ucsf.edu/draft-hhs-2023-framework-support-and-accelerate-smoking-cessation>

¹³ UCSF public comments supporting FDA's proposed Tobacco Product Standard for Menthol in Cigarettes, available at <https://tobacco.ucsf.edu/list-public-comments-fda-and-other-agencies-ucsf-faculty-and-fellows-and-others-links-comments> :

Actual human disease data contradicts the low assumed e-cigarette risk FDA uses to justify an exception for "reduced risk" cigarettes in its product standard prohibiting menthol;

FDA was correct in not quantifying consumer surplus in its analysis of the proposed standard for menthol in cigarette;

FDA's economic model underestimates the benefits of the proposed product standard prohibiting menthol in cigarettes, so the benefits would be even greater;

FDA should not grant exemptions to the proposed standard on a case-by-case basis for certain cigarettes such as heated tobacco products or low nicotine cigarettes;

FDA should prohibit all menthol flavor additives, compounds, constituents, and ingredients in cigarettes, and should not limit the proposed standard to prohibiting menthol as a "characterizing flavor";

As a matter of health equity and social justice, FDA should immediately finalize and implement the proposed standard for menthol in cigarettes to reduce smoking-attributable deaths and health disparities among African Americans;

Because of the tremendous health impacts that would accrue from the enactment of the 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.

The Food and Drug Administration's proposed rule to prohibit menthol in cigarettes will reduce youth and young adult initiation rates of smoking cigarettes and significantly reduce premature deaths and illnesses related to tobacco use.

¹⁴ UCSF public comments supporting FDA's proposed Tobacco Product Standard for Characterizing Flavors in Cigars, available at <https://tobacco.ucsf.edu/list-public-comments-fda-and-other-agencies-ucsf-faculty-and-fellows-and-others-links-comments> :

- FDA announced in January 2023 that it is currently drafting the final rules and is “committed to completing the rulemaking process in 2023.”¹⁵
- FDA should meet its self-imposed deadline of December 2023 to finalize these rules. It has had plenty of time (nearly 16 months as of August 2023 since FDA requested public comment on the proposed rule) to do this.
- As FDA stated, additional delays “would only increase the numbers of youth and young adults who experiment with menthol cigarettes and become regular smokers, delay cessation by current smokers, and exacerbate tobacco-related health disparities.”¹⁶
- As we stated in our June 1, 2022 public comment,¹⁷ every month delay in implementing the proposed menthol standard would result in an additional 29,403 new cigarette smokers.

2. CTP should finalize its pending menthol rules in ways that include menthol analogs, including WS-3 and similar cooling agents that mimic menthol in tobacco products.

- It is well understood that the perception of taste relies not only on the gustatory sense (chemoreceptors on the tongue) and the olfactory sense (sensory receptors in the nose,) but also on a third sensory system, the somatosensory system (also called the “chemesthetic” or “trigeminal sensation”), which is an integral contributor to taste and the flavor perception.

FDA should extend the scope of the proposed flavor standard to prohibit flavors in all tobacco products, including e-cigarettes and smokeless tobacco, to make them less appealing to adolescents and young adults;

FDA should extend the scope of the proposed standard prohibiting characterizing flavors in cigars to include e-cigarettes;

FDA’s proposed rule prohibiting characterizing flavors in cigars will reduce their appeal and will therefore reduce initiation rates, reduce tobacco-related deaths and diseases, and reduce health disparities; however, greater benefits will be realized if FDA prohibits flavors as additives and extends the scope of the rule to waterpipe;

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

FDA should deny any requests for extensions of time to submit public comments about the proposed rule on characterizing flavors in cigars.

¹⁵ Brian King, Looking Back, Looking Ahead: FDA’s Progress on Tobacco Product Regulation in 2022, January 31, 2023. Available: <https://www.fda.gov/tobacco-products/ctp-newsroom/looking-back-looking-ahead-fdas-progress-tobacco-product-regulation-2022>

¹⁶ US Food and Drug Administration, Tobacco Product Standard for Menthol in Cigarettes, May 4, 2022, Proposed Rule, 87 FR 26454 at 26489.

¹⁷ Wendy Max, Lauren Kass Lempert, Stanton Glantz, et al. FDA should finalize the proposed rule and make it effective 90 days after publication of the final rule, June 1, 2022. Available: <https://www.regulations.gov/comment/FDA-2021-N-1349-52739>

All three systems – the gustatory, olfactory, and somatosensory systems – work together to create the perception of flavor or taste.^{18, 19, 20, 21, 22, 23}

- Synthetic cooling agents such as WS-3 are found in several products that are being marketed to evade existing and proposed state and federal flavor and menthol prohibitions.²⁴ While they impart minty or cooling sensations similar to menthol, they are odorless.²⁵
- For example, RJ Reynolds’ website²⁶ provides lists of the ingredients contained in their products by specific brand families and brand styles. WS-3 is listed under the name, “n-Ethyl-p-Menthane-3-Carboxamide” and is found in the following brand varieties: Newport Non-menthol Green, Newport Non-menthol green 100, Newport EXP Mix, Newport EXP Mix 100, Newport EXP Max, Newport EXP Max 100, and Camel Crisp Non-menthol Green. All of these varieties are marketed in California where there is a statewide prohibition on selling tobacco products with “characterizing flavors,” which is defined as a “distinguishable taste or aroma, or both, other than the taste or aroma of tobacco.”²⁷
- FDA’s final rules should clarify that the prohibitions are intended to include products such as the RJ Reynolds varieties listed above that include menthol analogs such as WS-3 and similar cooling agents that impart a cooling sensation, and that the rules are not limited only to products that impart a distinct minty or menthol taste or aroma.
- FDA’s proposed product standards already include the foundation for such action. The proposed rule (21 CFR 1162.5) would establish a tobacco product standard prohibiting the use of menthol as a characterizing flavor in cigarettes. Although it does not explicitly define the term, “characterizing flavor,” FDA stated that “among the factors that FDA believes are relevant in determining whether a cigarette has a characterizing flavor [is] ... the *multisensory experience (i.e., taste, aroma, and cooling or burning sensations in the mouth and throat)* of a flavor during use of a tobacco product, including its components or parts...”²⁸ The proposed rule (21 CFR 1166.5) that would prohibit characterizing flavors in

¹⁸ Small DM, Green BG. A Proposed Model of a Flavor Modality. In: Murray MM, Wallace MT, editors. *The Neural Bases of Multisensory Processes*. Boca Raton (FL): CRC Press/Taylor & Francis; 2012. Chapter 36. PMID: 22593893. (<https://www.ncbi.nlm.nih.gov/books/NBK92876/>)

¹⁹ Running CA. Oral sensations and secretions. *Physiol Behav*. 2018 Sep 1;193(Pt B):234-237. doi: 10.1016/j.physbeh.2018.04.011. Epub 2018 Apr 10. PMID: 29653113.

²⁰ Krishnan-Sarin S, O'Malley SS, Green BG, Jordt SE. The science of flavour in tobacco products. *World Health Organ Tech Rep Ser*. 2019 Oct 24;1015:125-142. PMID: 36743396; PMCID: PMC9896977.

²¹ Delwiche J. The impact of perceptual interactions on perceived flavor. *Food Quality and Preference*. 2004; 15: 137-146.

²² Spence C. Multisensory flavour perception. *Curr Biol*. 2013 May 6;23(9):R365-9. doi: 10.1016/j.cub.2013.01.028.

²³ Jackler, Glantz, Lempert report, “Scientific Basis for Concluding the Newly Introduced California “non-Menthol” Cigarettes have a Characterizing Flavor,” March 1, 2023. Available: https://tobacco-img.stanford.edu/wp-content/uploads/2023/03/03091551/CoolingAgentsCharactizing_3-1-2023F.pdf) Also:

<https://profglantz.com/2023/03/02/non-menthol-is-a-characterizing-flavor-so-illegal-to-sell-in-california/>

²⁴ Meza LR, Galimov A, Sussman S, et al. Proliferation of ‘non-menthol’ cigarettes amid a state-wide flavour ban *Tobacco Control* Published Online First: 20 July 2023. doi: 10.1136/tc-2023-058074

²⁵ Jabba SV, Erythropel HC, Woodrow JG, et al. Synthetic Cooling Agent in Oral Nicotine Pouch Products Marketed as “Flavor-Ban Approved” *bioRxiv* 2023.02.23.529797; doi: <https://doi.org/10.1101/2023.02.23.529797>.

²⁶ <https://rjrt.com/commercial-integrity/ingredients/brand-compounds/>

²⁷ California Health and Safety Code section 104559.5(a)(1). Available at:

https://leginfo.ca.gov/faces/codes_displaySection.xhtml?lawCode=HSC§ionNum=104559.5

²⁸ US Food and Drug Administration, Tobacco Product Standard for Menthol in Cigarettes, May 4, 2022, Proposed Rule, 87 FR 26454 at 26455, 26488.

cigars adopts the identical language as the proposed menthol standard in cigarettes and states that FDA would consider a “cooling sensation” in the mouth and throat to be a relevant factor in determining whether a cigar has a characterizing flavor.²⁹

- FDA’s approach that would consider a cooling sensation in the mouth or throat as relevant to a determination that a tobacco product has a characterizing flavor is scientifically valid as explained above.
- In our previously submitted public comments, incorporated by reference, we urged FDA to prohibit menthol analogs as flavor additives, compounds, constituents, and/or ingredients in cigarettes³⁰ and cigars³¹ because the cooling sensation they provide can increase the products’ appeal.
- FDA has all the scientific evidence necessary, which is already in the public docket, to meet its self-imposed deadline of December 2023 to finalize these rules.

Conclusion:

Finalizing the proposed product standards for menthol in cigarettes and flavors in cigars is a specific action CTP could take in the next four months that would have tremendous impact in significantly reducing tobacco-related death and disease.

These actions would:

- markedly reduce the appeal of cigarettes and cigars, especially to adolescents, young adults, and other priority populations;
- substantially reduce tobacco-related health disparities and advance health equity; and
- minimize the likelihood that tobacco manufacturers will evade regulations designed to protect the public health.

²⁹ US Food and Drug Administration, Tobacco Product Standard for Characterizing Flavors in Cigars Proposed Rule, 87 FR 26396 at 26397, 26437.

³⁰ Lauren Kass Lempert, Stanton A Glantz, Andre Luiz Oliveira Da Silva, et al. FDA should prohibit all menthol flavor additives, compounds, constituents, and ingredients in cigarettes, and should not limit the proposed standard to prohibiting menthol as a “characterizing flavor,” Docket No. FDA-2021-N-1349, August 1, 2022. Available: <https://www.regulations.gov/comment/FDA-2021-N-1349-175335>

³¹ Lauren Kass Lempert, Stanton A Glantz, Gideon St.Helen, Andre Luiz Oliveira Da Silva, et al. FDA’s proposed rule prohibiting characterizing flavors in cigars will reduce their appeal and will therefore reduce initiation rates, reduce tobacco-related deaths and diseases, and reduce health disparities; however, greater benefits will be realized if FDA prohibits flavors as additives and extends the scope of the rule to waterpipe, Docket No FDA-2021-N-1309, August 1, 2022. Available: <https://www.regulations.gov/comment/FDA-2021-N-1309-71777>