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

Submitted via federalregister.gov

Re: Docket No. FDA-2021-N-1349 for “Tobacco Product Standard for Menthol in Cigarettes”

First Focus on Children appreciates the opportunity to submit comments in strong support of the proposed product standard prohibiting menthol as a characterizing flavor in cigarettes, which will reduce youth smoking, save lives, and advance health equity. The proposed rule will have an enormous public health impact both in the short and long term.

First Focus on Children is a bipartisan child advocacy organization dedicated to making children and families the priority in federal policy and budget decisions. As advocates for children, we are committed to ensuring that all children have an equal chance for success. Prohibiting menthol as a characterizing flavor in cigarettes will save and improve children’s lives, and we are in full support of this proposal.

Prohibiting menthol cigarettes will reduce youth smoking. In 2021, 34 percent of high school students and 11 percent of middle school students reported having used a tobacco product, with cigarettes being the second most popular.ⁱ Menthol in cigarettes cools and numbs the throat, reduces the harshness of tobacco smoke, and makes cigarettes more appealing to new smokers, particularly young people. As is well-documented in the proposed rule, menthol facilitates experimentation, progression to regular smoking of menthol cigarettes and contributes to greater nicotine dependence.ⁱⁱ Half of youth who have ever tried smoking started with menthol cigarettesⁱⁱⁱ and menthol cigarettes were responsible for 10.1 million additional new smokers between 1980 and 2018.^{iv} In 2021, 41 percent of high school smokers reported using menthol cigarettes.^v

Prohibiting menthol cigarettes will increase smoking cessation and save lives. Smoking remains the leading cause of preventable disease and death in the United States.^{vi} Prohibiting menthol cigarettes, which are more difficult to quit than non-menthol cigarettes, will reduce this burden by increasing smoking cessation.^{vii} As described in the rule, modeling studies have estimated that 324,000 to 654,000 smoking attributable deaths would be avoided by the year 2060 if menthol cigarettes were no longer available in the United States.^{viii} This includes both youth as well as adults who are caregivers to youth, therefore impacting young people in numerous ways. We also know that nearly all tobacco product use starts before the age of 18 – 90 percent of adults who smoke cigarettes reported starting use as children or youth.^{ix} Reducing youth tobacco use will save the lives of youth as well as adults.

Prohibiting menthol cigarettes would decrease tobacco-related health disparities and advance health equity, especially among Black youth, youth who identify as LGBTQ, and youth experiencing mental illness. Menthol cigarettes have caused substantial harm to public health, and particularly to Black Americans. For more than 60 years, the tobacco industry has targeted Black Americans with marketing and

price promotions for menthol cigarettes,^x and as a result, 85 percent of Black smokers smoke menthol cigarettes compared to 29 percent of white smokers.^{xi} In 2011, FDA's Tobacco Products Scientific Advisory Committee determined that menthol cigarettes are marketed disproportionately to young people and Black smokers.^{xii} In 2021, current tobacco use was reported by 14 percent of middle and high school students who identified as lesbian, gay, or bisexual compared to eight percent of heterosexual students, 19 percent of students who identified as transgender compared to eight percent not transgender, and 14 percent of students experiencing psychological distress compared to 5.5 percent of those who were not. Importantly, the proposed product standard is expected to substantially decrease tobacco-related health disparities and to advance health equity across population groups.

On behalf of all children, we urge the FDA to act swiftly to issue this lifesaving rule in final form. Thank you for the opportunity to submit a comment on this important rule. Please contact Averil Pakulis (averip@firstfocus.org) or Olivia Gomez (oliviag@firstfocus.org) with any questions.

Respectfully submitted,



Bruce Lesley
President, First Focus on Children

ⁱ Gentzke, A, et al., "Tobacco Product Use and Associated Factors Among Middle and High School Students—National Youth Tobacco Survey, United States, 2021," MMWR 71(5): 1-29, March 10, 2022, <https://www.cdc.gov/mmwr/volumes/71/ss/pdfs/ss7105a1-H.pdf>.

ⁱⁱ Tobacco Product Standard for Characterizing Flavors in Cigars, 87 Fed. Reg. 26396, 26463-26466 and 26469-26470 (proposed May 4, 2022) (to be codified at 21 C.F.R. pt. 1166)

ⁱⁱⁱ Ambrose, BK, et al., "Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014," *Journal of the American Medical Association*, published online October 26, 2015.

^{iv} Le, TT, "An Estimation of the Harm of Menthol Cigarettes in the United States from 1980 to 2018," *Tobacco Control*, published online on February 25, 2021.

^v Gentzke, A, et al., "Tobacco Product Use and Associated Factors Among Middle and High School Students—National Youth Tobacco Survey, United States, 2021," MMWR 71(5): 1-29, March 10, 2022, <https://www.cdc.gov/mmwr/volumes/71/ss/pdfs/ss7105a1-H.pdf>.

^{vi} U.S. Department of Health and Human Services (HHS). The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014

^{vii} Tobacco Product Standard for Characterizing Flavors in Cigars, 87 Fed. Reg. 26396, 26466-26468 and 26473-26477 (proposed May 4, 2022) (to be codified at 21 C.F.R. pt. 1166).

^{viii} Levy, D.T., J. Pearson, A. Villanti, et al. "Modeling the Future Effects of a Menthol Ban on Smoking Prevalence and Smoking-Attributable Deaths in the United States." *American Journal of Public Health*, 101:1236-1240, 2011. Available at <https://doi.org/10.2105/AJPH.2011.300179>. Levy, D.T., R. Meza, Z. Yuan, et al. "Public Health Impact of a US Ban on Menthol in Cigarettes and Cigars: A Simulation Study." *Tobacco Control*, 2021. Available at <https://doi.org/10.1136/tobaccocontrol-2021-056604>.

^{ix} Gentzke, A, et al., "Tobacco Product Use and Associated Factors Among Middle and High School Students—National Youth Tobacco Survey, United States, 2021," MMWR 71(5): 1-29, March 10, 2022, <https://www.cdc.gov/mmwr/volumes/71/ss/pdfs/ss7105a1-H.pdf>.

^x Gardiner, PS, "The African Americanization of menthol cigarette use in the United States," *Nicotine & Tobacco Research*, 6(S1): S55-S65, 2004. Yerger, VB, et al., "Racialized geography, corporate activity, and health disparities: Tobacco industry targeting of inner cities," *Journal of Health Care for the Poor and Underserved*, 18: 10-38, 2007. Hafez, N. & Ling, P.M. "Finding the Kool Mixx: how Brown & Williamson used music marketing to sell cigarettes," *Tobacco Control* 15: 359-366, 2006.

^{xi} Delnevo, CD, et al., “Banning Menthol Cigarettes: A Social Justice Issue Long Overdue,” *Nicotine & Tobacco Research*, 22(10): 1673-1675, 2020.

^{xii} TPSAC, Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations, July 21, 2011
<https://wayback.archiveit.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf>