

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

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

Action on Smoking and Health 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.

Founded in 1967, Action on Smoking and Health (ASH) is a U.S. based 501(c) (3) organization and one of the nation's oldest antismoking organizations. ASH was instrumental in the development of the WHO Framework Convention on Tobacco Control and continues to promote the implementation of its evidence-based measures. ASH's vision is to end the worldwide disease, damage and death caused by smoking and exposure to tobacco smoke. We work to do this through a human rights and health equity-based approach to tobacco control.

ASH has several concerns regarding the proposed rule:

Characterizing flavors

The rule proposes to prohibit menthol as a “characterizing flavor” in cigarettes, but that term has not been given a legal definition. Since May 2020, cigarettes with a characterizing flavor of menthol have been banned in the European Union (EU) owing to the European Tobacco Products Directive (EU TPD).ⁱ However, tobacco companies have exploited loopholes in the directive to continue to sell menthol products, which are still frequently being used.ⁱⁱ These loopholes allow for flavored tobacco accessories, recessed cigarette filters, and design/brand descriptions that create the impression of menthol.ⁱⁱⁱ ASH strongly encourages the FDA to confer with other governments around the world who have implemented menthol bans, in order to learn from their successes and missteps. And further, in order to prevent these loopholes, ASH encourages the FDA to consider banning ALL menthol. In lieu of that best practice, the FDA should create a rule with a strong legal definition that is not able to be easily circumvented by the tobacco industry.

Exemptions

Action on Smoking and Health would like to strongly discourage any exemptions, including for heated cigarette products like iQOS or so-called Very Low Nicotine (VLN) cigarettes from this rule. Given the potential harm of these products, it is critical that they not be exempted from the proposed standard. The proposed rule indicated that the FDA is considering establishing a process by which a manufacturer could request an exemption from the standard for a particular product on a case-by-case basis. Action on Smoking and Health strongly discourages any exemptions to ensure the strongest possible public health benefit from the final rule.



Timeline

The FDA has proposed that this rule would take effect one year after the final rule is issued. Given the number of lives that the rule would save, Action on Smoking and Health strongly urges the FDA to act more quickly to get the final regulation in place.

Despite these concerns, ASH is highly in favor of prohibiting menthol cigarettes for these reasons:

Prohibiting menthol cigarettes will reduce youth smoking.

Menthol 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.^{iv} Half of youth who have ever tried smoking started with menthol cigarettes^v and menthol cigarettes were responsible for 10.1 million additional new smokers between 1980 and 2018.^{vi}

Prohibiting menthol cigarettes will increase smoking cessation and save lives.

Smoking remains the leading cause of preventable disease and death in the United States.^{vii} Prohibiting menthol cigarettes, which are more difficult to quit than non-menthol cigarettes, will reduce this burden by increasing smoking cessation.^{viii} 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.^{ix}

Prohibiting menthol cigarettes would decrease tobacco-related health disparities and advance health equity, especially among Black Americans.

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% of Black smokers smoke menthol cigarettes compared to 29% of White smokers.^{xi} Consequently, Black Americans are less likely to successfully quit smoking^{xii} and suffer disproportionately from tobacco-related disease and death.^{xiii} Despite accounting for 12% of the population, Black Americans represented 41% of premature deaths caused by menthol cigarettes between 1980 and 2018.^{xiv} In addition to youth and Black smokers, preference for menthol is also disproportionately high among Hispanic and Asian smokers, lesbian, gay, and bisexual smokers, smokers with mental health problems, socioeconomically disadvantaged populations, and pregnant women.^{xv} Importantly, the proposed product standard is expected to substantially decrease tobacco-related health disparities and to advance health equity across population groups. In order to further reduce health disparities, ASH encourages the FDA to support culturally competent education and cessation support programs.

We urge the FDA to act swiftly to issue this lifesaving rule in final form.

Respectfully submitted,

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- ⁱ European Union. Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the member states concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC. *Off J Eur Union* 2014;127:1–38.
- ⁱⁱ Brink A, Glahn AS, Kjaer NT. Tobacco companies' exploitation of loopholes in the EU ban on menthol cigarettes: a case study from Denmark. *Tobacco Control*. Published Online First: 21 March 2022. doi: 10.1136/tobaccocontrol-2021-057213.
- ⁱⁱⁱ Brink A, Glahn AS, Kjaer NT. Tobacco companies' exploitation of loopholes in the EU ban on menthol cigarettes: a case study from Denmark. *Tobacco Control*. Published Online First: 21 March 2022. doi: 10.1136/tobaccocontrol-2021-057213.
- ^{iv} 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).
- ^v 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.
- ^{vi} 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.
- ^{vii} 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.
- ^{viii} 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).
- ^{ix} 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>.
- ^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} CDC, "Current Cigarette Smoking Among Adults—United States, 2005-2015," *Morbidity & Mortality Weekly Report*, 65(44): 1205-1211, November 11, 2016, http://www.cdc.gov/mmwr/volumes/65/wr/mm6544a2.htm?s_cid=mm6544a2_w.
- ^{xiii} CDC, "Vital Signs: Disparities in Tobacco-Related Cancer Incidence and Mortality—United States, 2004-2013," *Morbidity & Mortality Weekly Report*, 65(44): 1212-1218, <http://www.cdc.gov/mmwr/volumes/65/wr/mm6544a3.htm>.; See also American Cancer Society. Cancer Facts & Figures for African American/Black People 2022-2024. Atlanta: American Cancer Society, 2022. HHS, "Tobacco Use Among US Racial/Ethnic Minority Groups—African Americans, American Indians and Alaskan Natives, Asian Americans and Pacific Islanders, and Hispanics: A Report of the Surgeon General," 1998, http://www.cdc.gov/tobacco/data_statistics/sgr/1998/complete_report/pdfs/complete_report.pdf.
- ^{xiv} Mendez, D and Le, TT, "Consequences of a match made in hell: the harm caused by menthol smoking to the African American population over 1980-2018," *Tobacco Control*, published online September 16, 2021.
- ^{xv} Delnevo, CD, et al., "Banning Menthol Cigarettes: A Social Justice Issue Long Overdue," *Nicotine & Tobacco Research*, 22(10): 1673-1675, 2020.