FDA'S ACTION ON MENTHOL AND FLAVORED CIGARS

What happens now?

The FDA's Announcement

On April 29th, 2021, the FDA issued a formal response to the 2013 citizen petition and 2021 supplement filed by the Public Health Law Center in partnership with the African American Tobacco Control Leadership Council (AATCLC), the Center for Black Health and Equity (formerly NAATPN), and other public health groups, asking the agency to remove menthol as a characterizing flavor in cigarettes. In the simplest terms, **the agency granted the petition and intends to begin the rulemaking process to prohibit menthol in cigarettes**. It is important to note that this decision comes only as a result of litigation by AATCLC, Action on Smoking and Health, and other public health advocacy groups.

The FDA also issued a press release on the same day, expanding on the commitment in the formal response and laying out its plans to further protect public health and advance health equity by **also banning *all* characterizing flavors (including menthol) in cigars** – importantly, this includes little cigars and cigarillos.

Joelle Lester, Dr. Valerie Yerger, and Doug Blanke at FDA headquarters hand-delivering the original petition requesting the FDA ban menthol in cigarettes. (April 12, 2013)

In the press release, Mitch Zeller, J.D., director of the FDA's Center for Tobacco Products, stated:

> For far too long, certain populations, including African Americans, have been targeted, and disproportionately impacted by tobacco use. Despite the tremendous progress we've made in getting people to stop smoking over the past 55 years, *that progress hasn't been experienced by everyone equally*...These flavor standards would *reduce cigarette and cigar initiation and use, reduce health disparities, and promote health equity by addressing a significant and disparate source of harm*. Taken together, these policies will help save lives and improve the public health of our country as we confront the leading cause of preventable disease and death. (Emphasis added).

In other words, the FDA signaled that meeting the Tobacco Control Act's legal standard of what is "appropriate for the protection of the public health" includes action that will reduce health disparities and promote health equity.

Doug Blanke, Dr. Phil Gardner, Carol McGruder, Dr. Valerie Yerger, Delmonte Jefferson, and Joelle Lester – representing the partnership between the African American Tobacco Control Leadership Council, the Center for Black Health and Equity, and Public Health Law Center; unyielding champions and "game-changers" in the fight to ban menthol. (August 27, 2019)

The citizen petition response also indicates that the FDA intends to collaborate with other federal agencies and Tribal, state, and local entities to provide cessation support to menthol smokers who want to quit smoking. Coupling cessation support with bold policy action is critical to effectively reducing health disparities and promoting health equity.

What Happens Next?

The FDA's citizen petition response states that the agency intends to make this proposed rule one of its "highest priorities." In the press release, the FDA states that it intends to issue the proposed product standards "within the next year." The acting FDA Commissioner has also explicitly directed the Center for Tobacco Products to begin drafting the rule "promptly".

While this is the first step in seeing the harm from menthol cigarettes and flavored cigars eradicated, this does not mean that the menthol and flavored cigar ban will become effective within a year. The agency will first issue a "proposed rule," which will describe the evidence and the agency's proposed course of action. That rule will be published in the Federal Register and on Regulations.gov triggering a public comment period. When the comment period is closed, the FDA will decide whether to issue a final rule. Before a final rule can be published, the FDA will: draft the rule and respond to public comments received during the comment period, get feedback from other concerned federal agencies, and seek clearance from the Office of Management and Budget.

After the FDA publishes a final rule, the Tobacco Control Act requires an effective date at least one year after the publication of the final rule. However, the FDA can establish an earlier finally removed from store shelves nationwide is to withstand any litigation challenges by the industry. effective date if it determines it is appropriate for the protection of public health to do so.[1] This means that, in all likelihood, a menthol and flavored cigar ban will not take effect for several months to years. Finally, the last hurdle before menthol cigarettes and flavored cigars are finally removed from store shelves nationwide is to withstand any litigation challenges by the industry.

How can you participate/help?

Advocates should continue to hold the FDA accountable and demand swift progress towards a final rule and timely effective date. At the same time, given the slow pace of rulemaking and

[1] 21 USC 387g (c)(2)

potential litigation delays, Tribal, state, and local action to ban menthol and all flavors in all tobacco products cannot wait. Many communities have already taken bold action to address the harms of flavored tobacco products, including menthol, and that work should continue. In fact, the FDA's conclusions in the response and press release about the overwhelming science surrounding the damaging impact of menthol and flavored tobacco products should help support these important efforts.

As the rulemaking process unfolds, it is also important that the agency hear the public's voice through public comments about the critical importance of this rule. Once the proposed rule is published, the public health community is encouraged to submit comments to the FDA through the federal regulatory portal, Regulations.gov. The Public Health Law Center has two publications aimed at helping write public comments: Telling the Public Health Story to the FDA and Getting Scientific Research to the FDA. For up to date information on any menthol-related FDA action, you can subscribe to the Public Health Law Center's monthly newsletter and regularly check publichealthlawcenter.org and the FDA Action Center.

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