



July 19, 2021

Anthony Albanese, MD, DFASAM
President
California Society of Addiction Medicine
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Sacramento, CA 95814
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Dear Dr. Albanese:

Thank you for your letter of April 19, 2021, addressed to Dr. Janet Woodcock, Acting Commissioner of Food and Drugs, regarding the Food and Drug Administration's (FDA or Agency) regulation of menthol cigarettes. Dr. Woodcock asked me to respond to you on her behalf.

We appreciate your comments regarding the scientific support for a ban on menthol and other flavors in combusted tobacco products. On April 29, 2021, FDA announced it is committing to advancing two tobacco product standards to significantly reduce disease and death from using combusted tobacco products, the leading cause of preventable death in the United States. FDA is working toward issuing proposed product standards by the end of April 2022 to ban menthol as a characterizing flavor in cigarettes and ban all characterizing flavors (including menthol) in cigars. 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.

On that same date, FDA also granted a citizen petition requesting the Agency pursue rulemaking to prohibit menthol as a characterizing flavor in cigarettes, affirming our commitment to proposing such a product standard. This decision is based on clear science and evidence establishing the addictiveness of these products and builds on important, previous actions that banned other flavored cigarettes in 2009. There is strong evidence that a menthol ban will help people quit. Studies show that menthol increases the appeal of tobacco and facilitates progression to regular smoking, particularly among youth and young adults. Menthol masks unpleasant flavors and harshness of tobacco products, making them easier to start using. Tobacco products with menthol can also be more addictive and harder to quit by enhancing the effects of nicotine.

As described above, by the end of April 2022, FDA aims to publish in the *Federal Register* two proposed rules related to banning menthol as a characterizing flavor in cigarettes and banning all characterizing flavors (including menthol) in cigars. After a proposed rule is published, there is a public comment period during which the Agency solicits feedback and comments from the public on the proposal. In developing any final rule that follows, the Agency will explain the

regulatory requirements, the impact of these requirements on industry or the public, and respond to the comments on the proposed rule. FDA encourages all interested stakeholders to participate in this process.

Thank you, again, for your interest in this public health issue.

Sincerely,



Mitchell Zeller
Director, Center for Tobacco Products