

FDA NEWS RELEASE

FDA Proposes Rules Prohibiting Menthol Cigarettes and Flavored Cigars to Prevent Youth Initiation, Significantly Reduce Tobacco-Related Disease and Death



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Today, the U.S. Food and Drug Administration is announcing proposed product standards [to prohibit menthol as a characterizing flavor in cigarettes](#) and prohibit [all characterizing flavors \(other than tobacco\) in cigars](#). These actions have the potential to significantly reduce disease and death from combusted tobacco product use, the leading cause of preventable death in the U.S., by reducing youth experimentation and addiction, and increasing the number of smokers that quit.

“The proposed rules would help prevent children from becoming the next generation of smokers and help adult smokers quit,” said Health and Human Services Secretary Xavier Becerra. “Additionally, the proposed rules represent an important step to advance health equity by significantly reducing tobacco-related health disparities.”

These proposed product standards are based on clear science and evidence establishing the addictiveness and harm of these products and build on the Family Smoking Prevention and Tobacco Control Act, which prohibited all characterizing flavors (other than tobacco and menthol) in cigarettes in 2009. They are also a critical piece of the Administration’s reignited Cancer Moonshot to reduce the death rate from cancer by at least 50 percent over the next 25 years; tobacco use is a leading cause of cancer and death from cancer, and approximately 30 percent of all cancer deaths in the United States are caused by smoking.

“The authority to adopt tobacco product standards is one of the most powerful tools Congress gave the FDA and the actions we are proposing can help significantly reduce youth initiation and increase the chances that

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current smokers quit. It is clear that these efforts will help save lives,” said FDA Commissioner Robert M. Califf, M.D. “Through the rulemaking process, there’s an important opportunity for the public to make their voices heard and help shape the FDA’s ongoing efforts to improve public health.”

Menthol product standard would have significant public health impact

Menthol is a flavor additive with a minty taste and aroma that reduces the irritation and harshness of smoking. This increases appeal and makes menthol cigarettes easier to use, particularly for youth and young adults. Menthol also interacts with nicotine in the brain to enhance nicotine’s addictive effects. The combination of menthol’s flavor, sensory effects and interaction with nicotine in the brain increases the likelihood that youth who start using menthol cigarettes will progress to regular use. Menthol also makes it more difficult for people to quit smoking.

In 2019, there were more than 18.5 million current menthol cigarette smokers ages 12 and older in the U.S., with particularly high rates of use by youth, young adults, and African American and other racial and ethnic groups. Published modeling studies have estimated a 15 percent reduction in smoking within 40 years if menthol cigarettes were no longer available in the United States. These studies also estimate that 324,000 to 654,000 smoking attributable deaths overall (92,000 to 238,000 among African Americans) would be avoided over the course of 40 years.

When finalized, the proposed menthol product standard will:

- reduce the appeal of cigarettes, particularly to youth and young adults, decreasing the likelihood that nonusers who would otherwise experiment with menthol cigarettes would progress to regular smoking; and
- improve the health and reduce the mortality risk of current menthol cigarette smokers by decreasing cigarette consumption and increasing the likelihood of cessation.

Flavored cigar product standard would reduce youth risk

Characterizing flavors in cigars, such as strawberry, grape, cocoa and fruit punch, increase appeal and make cigars easier to use, particularly among youth and young adults. More than a half million youth in the U.S. use flavored cigars, and in recent years more young people tried a cigar every day than tried a cigarette.

When finalized, this product standard will:

- reduce the appeal of cigars, particularly to youth and young adults, and decrease the likelihood of experimentation, development of nicotine dependence, and progression to regular use; and
- improve public health by increasing the likelihood that existing cigar smokers may quit.

Importantly, the FDA cannot and will not enforce against individual consumers for possession or use of menthol cigarettes or flavored cigars. If

these proposed rules are finalized and implemented, FDA enforcement will only address manufacturers, distributors, wholesalers, importers and retailers who manufacture, distribute, or sell such products within the U.S. that are not in compliance with applicable requirements. These proposed regulations do not include a prohibition on individual consumer possession or use.

State and local law enforcement agencies do not independently enforce the Federal Food, Drug and Cosmetic Act and do not, and cannot, take enforcement actions against any violation of FDA's tobacco authorities, including its regulations, on the FDA's behalf. However, the agency recognizes concerns related to how state and local law enforcement may enforce their own laws in a manner that may impact equity and community safety, particularly for underserved and underrepresented communities. The FDA is seeking comment on, among other things, how it can best make clear the respective roles of the agency and state and local law enforcement, as well as policy considerations related to the potential racial and social justice implications of the proposed product standards.

Beginning May 4, 2022, the public can provide comments on these proposed rules, which the FDA will review as it considers future action. The agency also will convene [public listening sessions](#) on June 13 and June 15 to expand direct engagement with the public, including affected communities. The listening sessions are another opportunity for individuals, communities, and organizations to share their perspectives with the FDA and will be recorded and submitted to the dockets.

The public will have the opportunity to submit either electronic or written comments directly to the dockets on the proposed rules through July 5, 2022. Once all the comments have been reviewed and considered, the FDA will decide whether to issue final product standards.

The agency also recognizes the importance of ensuring broad and equitable access to all the tools and resources that can help smokers quit. The FDA and HHS are working with federal partners to make sure the support is there for those who are trying to quit, especially in underserved communities. Many insurance plans cover tobacco cessation services, like medication and counseling, without any out-of-pocket cost. Smokers interested in quitting today should visit smokefree.gov or call 1-800-QUIT-NOW to learn about cessation services available in their state.

Related Information

- [Fact Sheet: Proposed product standards to prohibit menthol as a characterizing flavor in cigarettes and all characterizing flavors \(other than tobacco\) in cigars](#)
- [2013 Menthol in Cigarettes, Tobacco Products; Request for Comments](#)
- [FDA: Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes](#)

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veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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