

Fact Sheet:

Proposed product standards to prohibit menthol as a characterizing flavor in cigarettes and all characterizing flavors (other than tobacco) in cigars



The U.S. Food and Drug Administration has announced proposed product standards to:

- Prohibit menthol as a characterizing flavor in cigarettes.
- 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. Given that tobacco use is a leading cause of cancer and death from cancer, they are also a critical piece of the Administration's Cancer Moonshot to end cancer as we know it.

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.

▶ What is menthol and how is it used in cigarettes?

Menthol is a flavor additive with a minty taste and aroma that is widely used in consumer and medicinal products due to its reported cooling or painkilling properties.

Menthol's flavor and sensory effects make menthol cigarettes more appealing and easier to use particularly among new tobacco users, such as youth and young adults. It also interacts with nicotine in the brain to enhance nicotine's addictive effects and makes it more difficult for people to quit smoking.

The proposed menthol product standard would:

- 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.
- Improve the health and reduce the mortality risk of current menthol cigarette smokers by decreasing cigarette consumption and increasing the likelihood of cessation.

The impact of menthol on society:

- Nearly 85% of all non-Hispanic Black smokers use menthol cigarettes, compared to 30% of non-Hispanic White smokers.
- From 2011 to 2018, declines in menthol cigarette use were observed among non-Hispanic White youth but not among non-Hispanic Black or Hispanic youth.
- Published modeling studies have estimated a 15% reduction in smoking within 40 years if menthol cigarettes were no longer available in the U.S. 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.

▶ What are cigars and how do flavors contribute to their use?

A cigar is a roll of tobacco wrapped in leaf tobacco or in a substance that contains tobacco. They vary in size—from smaller cigars, such as little filtered cigars or cigarillos, to larger ones, such as large so-called premium cigars. Characterizing flavors in cigars, such as strawberry, grape, cocoa and fruit punch increase appeal and make cigars more popular and easier to use by youth and young adults.

When finalized, this product standard would:

- 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.
- Improve public health by increasing the likelihood that existing cigar smokers may quit.

The impact of flavored cigars on society:

- According to the 2020 National Youth Tobacco Survey (NYTS), an estimated 3.5% (960,000) of middle and high school students, had smoked a cigar, cigarillo, or little cigar in the preceding 30 days.
- Each year, an estimated 9,000 premature deaths are attributed to regular cigar smoking; approximately 5,200 of these premature deaths occur in cigar smokers who do not also currently smoke cigarettes.
- In 2019, more young adults tried a cigar for the first time each day than tried a cigarette for the first time (3,163 cigar vs. 2,640 cigarette initiates per day).
- Data from the 2020 NYTS show more than half (58.3%) of youth cigar smokers, or about 550,000 youth, reported using a flavored cigar, little cigar or cigarillo during the past 30 days.
- Study findings also indicate racial and ethnic disparities in cigar product use. The 2020 NYTS data show that cigars are especially popular among non-Hispanic Black middle and high school students, as 6.5% reported past 30-day cigar use compared to 2.8% of non-Hispanic White students.