

**FDA News Release**

# FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death

*Agency to pursue lowering nicotine in cigarettes to non-addictive levels and create more predictability in tobacco regulation*

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**For Immediate  
Release**

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**Release**

The U.S. Food and Drug Administration today announced a new comprehensive plan for tobacco and nicotine regulation that will serve as a multi-year roadmap to better protect kids and significantly reduce tobacco-related disease and death. The approach places nicotine, and the issue of addiction, at the center of the agency's tobacco regulation efforts. The goal is to ensure that the FDA has the proper scientific and regulatory foundation to efficiently and effectively implement the Family Smoking Prevention and Tobacco Control Act. To make certain that the FDA is striking an appropriate balance between regulation and encouraging development of innovative tobacco products that may be less dangerous than cigarettes, the agency is also providing targeted relief on some timelines described in the May 2016 final rule that extended the FDA's authority to additional tobacco products. The agency will also seek input on critical public health issues such as the role of flavors in tobacco products.

Tobacco use remains the leading cause of preventable disease and death in the United States, causing more than 480,000 deaths every single year. In addition to the devastating human toll caused mainly by cigarette smoking, tobacco also causes substantial financial costs to society, with direct health care and lost productivity costs totaling nearly \$300 billion a year. A key piece of the FDA's approach is demonstrating a greater awareness that nicotine – while highly addictive – is delivered through products that represent a continuum of risk and is most harmful when delivered through smoke particles in combustible cigarettes.

“The overwhelming amount of death and disease attributable to tobacco is caused by addiction to cigarettes – the only legal consumer product that, when used as intended, will kill half of all long-term users,” said FDA Commissioner Scott Gottlieb, M.D. “Unless we change course, 5.6 million young people alive today will die

prematurely later in life from tobacco use. Envisioning a world where cigarettes would no longer create or sustain addiction, and where adults who still need or want nicotine could get it from alternative and less harmful sources, needs to be the cornerstone of our efforts – and we believe it’s vital that we pursue this common ground.”

The FDA plans to begin a public dialogue about lowering nicotine levels in combustible cigarettes to non-addictive levels through achievable product standards. The agency intends to issue an Advance Notice of Proposed Rulemaking (ANPRM) to seek input on the potential public health benefits and any possible adverse effects of lowering nicotine in cigarettes. Because almost 90 percent of adult smokers started smoking before the age of 18 and nearly 2,500 youth smoke their first cigarette every day in the U.S., lowering nicotine levels could decrease the likelihood that future generations become addicted to cigarettes and allow more currently addicted smokers to quit.

“Because nicotine lives at the core of both the problem and the solution to the question of addiction, addressing the addictive levels of nicotine in combustible cigarettes must be part of the FDA’s strategy for addressing the devastating, addiction crisis that is threatening American families,” said Commissioner Gottlieb. “Our approach to nicotine must be accompanied by a firm foundation of rules and standards for newly-regulated products. To be successful all of these steps must be done in concert and not in isolation.”

The FDA is committed to encouraging innovations that have the potential to make a notable public health difference and inform policies and efforts that will best protect kids and help smokers quit cigarettes. To make this effort successful, the agency intends to extend timelines to submit tobacco product review applications for newly regulated tobacco products that were on the market as of Aug. 8, 2016. This action will afford the agency time to explore clear and meaningful measures to make tobacco products less toxic, appealing and addictive. For example, the FDA intends to develop product standards to protect against known public health risks such as electronic nicotine delivery systems (ENDS) battery issues and concerns about children’s exposure to liquid nicotine. It also will provide manufacturers additional time to develop higher quality, more complete applications informed by additional guidance from the agency.

The agency plans to issue this guidance describing a new enforcement policy shortly. Under expected revised timelines, applications for newly-regulated combustible products, such as cigars, pipe tobacco and hookah tobacco, would be submitted by Aug. 8, 2021, and applications for non-combustible products such as ENDS or e-cigarettes would be submitted by Aug. 8, 2022. Additionally, the FDA expects that manufacturers would continue to market products while the agency reviews product applications.

Importantly, the anticipated new enforcement policy will not affect any current requirements for cigarettes and smokeless tobacco, only the newly-regulated tobacco products such as cigars and e-cigarettes. This approach also will not apply to provisions of the final rule for which compliance deadlines already have passed, such as mandatory age and photo-ID checks to prevent illegal sales to minors. It also will not affect future deadlines for other provisions of the rule, including, but not limited to, required warning statements, ingredient listing, health document submissions, harmful and potentially harmful constituent reports, and the removal of modified risk claims, i.e., "light," "low," or "mild," or similar descriptors.

In order to further explore how best to protect public health in the evolving tobacco marketplace, the agency also will seek input from the public on a variety of significant topics, including approaches to regulating kid-appealing flavors in e-cigarettes and cigars. In particular, the FDA intends to issue ANPRMs to: 1) seek public comment on the role that flavors (including menthol) in tobacco products play in attracting youth and may play in helping some smokers switch to potentially less harmful forms of nicotine delivery; and 2) solicit additional comments and scientific data related to the patterns of use and resulting public health impacts from premium cigars, which were included in the FDA's 2016 rule. Additionally, the agency plans to examine actions to increase access and use of FDA-approved medicinal nicotine products, and work with sponsors to consider what steps can be taken under the safety and efficacy standard for products intended to help smokers quit.

“This comprehensive plan and sweeping approach to tobacco and nicotine allows the FDA to apply the powerful tools given by Congress to achieve the most significant public health impact,” said Mitch Zeller, J.D., director of the FDA's Center for Tobacco Products. “Public input on these complex issues will help ensure the agency has the proper science-based policies in place to meaningfully reduce the harms caused by tobacco use.”

To complement these larger policy considerations, the FDA plans to issue foundational rules to make the product review process more efficient, predictable, and transparent for manufacturers, while upholding the agency's public health mission. Among other things, the FDA intends to issue regulations outlining what information the agency expects to be included in Premarket Tobacco Applications (PMTAs), Modified Risk Tobacco Product (MRTP) applications and reports to demonstrate Substantial Equivalence (SE). The FDA also plans to finalize guidance on how it intends to review PMTAs for ENDS. The agency also will continue efforts to assist industry in complying with federal tobacco regulations through online information, meetings, webinars and guidance documents.

The FDA, an agency within the U.S. Department of Health and Human Services, promotes and protects the public health by, among other things, assuring the safety, effectiveness, and security of human and 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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### Related Information

- [Protecting American Families: Comprehensive Approach to Nicotine and Tobacco \(/NewsEvents/Speeches/ucm569024.htm\)](/NewsEvents/Speeches/ucm569024.htm)
- [FDA Center for Tobacco Products \(/TobaccoProducts/default.htm\)](/TobaccoProducts/default.htm)

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