



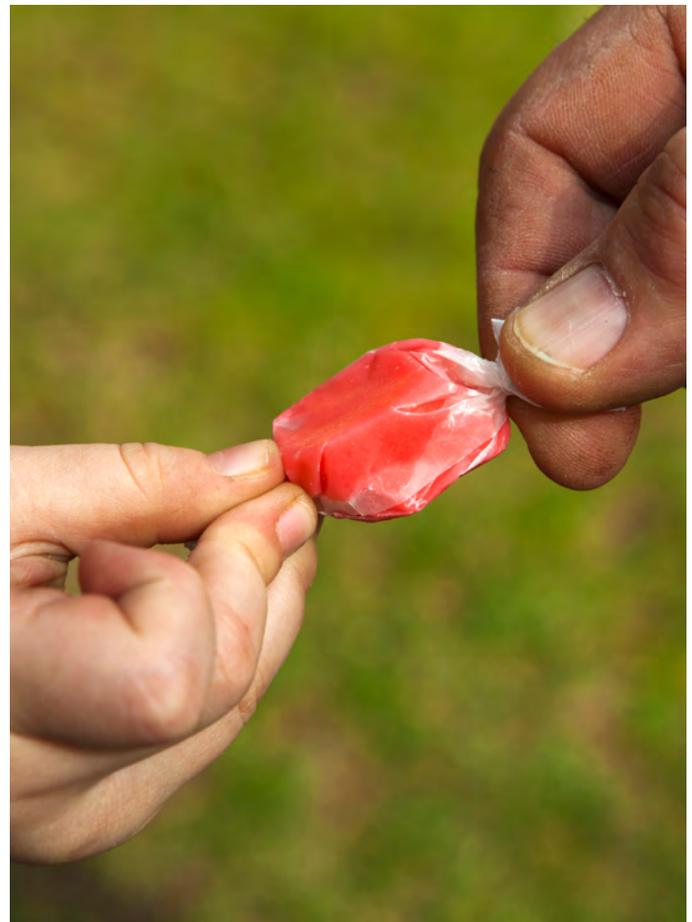
REGULATION OF FLAVORS IN TOBACCO PRODUCTS

Questions & Talking Points for Public Health Professionals



On March 21, 2018, the U.S. Food and Drug Administration (FDA) issued an Advance Notice of Proposed Rulemaking (ANPRM) to obtain information related to “the role that flavors play in tobacco products.”

This is a major part of the agency’s new regulatory plan for tobacco products. With this docket, the FDA is gathering scientific evidence, field research, and other useful information regarding youth initiation of commercial tobacco products through the attraction of flavors and whether flavors play a part in helping adult combustible commercial tobacco users transition to other, potentially less harmful products. Public health stakeholders can and should engage fully in the FDA’s process by presenting the evidence base for comprehensive rulemaking and encouraging the FDA to establish rules that are the most protective of the public’s health. The first step in that process is commenting on this ANPRM.



It is particularly important to tell the FDA that:

- The evidence on the public health impact of menthol in cigarettes is clear. The Tobacco Products Scientific Advisory Committee and the FDA's own scientists have concluded that the removal of menthol would benefit public health. The agency has already issued an ANPRM on this topic. There is an abundance of scientific evidence and every additional delay means additional lives lost. The FDA needs to act on menthol now.
- If the FDA moves forward with a comprehensive nicotine standard while prohibiting flavors, there is no need to exempt any flavor or any class of products with a goal of incentivizing adult smokers to switch to less harmful products; the nicotine standard for combustible products creates a much greater incentive for smokers to stop using combustible products.

Unlike a Notice of Proposed Rulemaking, which solicits comments on the language and content of a proposed rule, an ANPRM allows an agency to gather information about a topic to inform a future FDA rule. In this case, the public health community has an opportunity to shape the FDA's proposal before it is written. To that end, the FDA is gathering scientific evidence, field research, and other useful information that will assist the agency in determining the scope of a future product standard and the best way to implement and enforce such a standard. The agency's questions from the notice are compiled and categorized below. Consider answering these questions as you draft and submit your comment.

Use of Flavors by Various Age Groups*

The FDA asks for any evidence, research, or information about the role of flavors (other than tobacco):

- In general. And if such information is extrapolated from other research areas, an explanation of the commenter's rationale.
- Especially among youth and young adults:
 - In initiation and patterns of tobacco product use for combusted and noncombusted tobacco products.
 - In progression to other tobacco products (for example, noncombusted to combusted products).
- Especially for adult combusted tobacco users:
 - In helping switch from to potentially less harmful tobacco products.

* Where the FDA asks for information about populations, the FDA also requests that a commenter include definitions for those populations (i.e. youth, young adults, adults, etc.).



- In noncombusted products, among all current and former tobacco user populations the likelihood of:
 - Increased or decreased cessation of combusted tobacco or all tobacco product use.
 - Uptake of dual use of combusted and noncombusted tobacco products.
 - Delayed or impeded cessation among users who would have otherwise quit combusted tobacco or all tobacco product use.
 - Relapse by former tobacco users.

Full Text of the FDA's Questions [A\(1\)](#), [B\(2\)](#), [B\(3\)](#), [B\(4\)](#), [C\(5\)](#), [C\(6\)](#), [C\(7\)](#), [C\(8\)](#)

The Impact of State and Local Restrictions on Flavored Products

The FDA also asks for any studies or information on the impact, intended or unintended, of flavor restrictions imposed by local jurisdictions, states, and international communities, including restrictions on the manufacturing, marketing, sale, or distribution of all or a subset of tobacco products with flavors among all populations.

Question [D\(10\)](#)

The Scope of FDA Regulation

Regarding all flavors, the FDA asks which tobacco products (e.g., combusted, noncombusted, both) should a product standard prohibiting or restricting flavors apply to and why.

Question [E\(14\)](#)

Menthol in Cigarettes

In regard to menthol flavor, the FDA asks for data, evidence, or information about the role that:

- Menthol plays in cigarette smoking initiation and in the likelihood of smoking cessation for all populations (youth, young adult, adult). Including any new or additional information since the previously released 2013 ANPRM on menthol in cigarettes ([78 FR 444484](#), July 24 2013).
- A menthol product standard would play in the likelihood that tobacco users would completely switch to another tobacco product or start dual use with another tobacco product.
- Menthol plays in the use of products other than cigarettes, including, but not limited to, cigars and e-cigarettes.

Questions [E\(15\)\(a\)](#), [\(b\)](#), [\(c\)](#)

Specific Flavors

The FDA asks if there are any flavors that especially appeal to youth, young adults, or other specific age groups. And if so, how are such flavors distinguished from other flavors.

Question [G\(22\)](#)

Other Restrictions on Flavored Products

The FDA reveals that it may consider restrictions:

- On the sale and distribution of flavored tobacco products, including advertising and promotion of tobacco products with flavors.
- On access to tobacco products with flavors.
- On the label, labeling, and/or packaging of tobacco products with flavors.

These could include requirements to bear warnings or disclosure statements. The FDA seeks input on which restrictions to consider and why.

Question [F\(16\)](#)

Other Regulatory Actions

Additionally, the FDA has some catchall questions regarding whether any other tobacco product standard, regulatory action, or other action it could consider would:

- More effectively reduce the harms caused by flavors in tobacco products to better protect public health.
- Complement or increase the effectiveness of a flavor product standard.

Questions [G\(20\)](#), [G\(21\)](#)

Economic Impact of Regulation

The FDA must complete an economic analysis of a new rule restricting flavors. To that end, the FDA asks how it should assess and balance the benefits and risks of such a rule—namely, the extent to which flavors may pose both:

- Potential benefits to adult smokers who might consider switching to a noncombusted flavored tobacco product with lower individual risk.



- Potential risks to nonusers who might initiate use of tobacco products through flavored tobacco products.
- Potential risks to current users who might progress to flavored tobacco products with higher individual risk.

Question G(17)

This is a summary of questions the FDA has asked. Public health professionals preparing comments can reference the Public Health Law Center's publications *Getting Scientific Research to the FDA* and *Telling the Public Health Story to the FDA*.

Visit the Public Health Law Center's FDA Action Center for the latest developments related to the FDA's regulation of tobacco products, including additional information on the flavor ANPRM.

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