REGULATION OF FLAVORS IN TOBACCO PRODUCTS

Questions & Talking Points for Nicotine & Tobacco Researchers

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.

The rulemaking process is often a long process that is measured in years rather than days or months. Because of this, researchers can also see the FDA’s questions as potential gaps in the scientific knowledge that could be answered through modifying existing projects or aims (for example, adding questions to a survey) or that could be addressed in future grant proposals. Scientists should also feel encouraged to share with the FDA any new research or data that is developed on this topic, even after the end of the comment period.

It is particularly important to tell the FDA that:

- The evidence on the public health harms 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 from cigarettes 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 that more lives are lost. The FDA must act on menthol now.

- If the FDA moves forward with a comprehensive nicotine standard concurrently with a prohibition on 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.
The Role of Flavors (Other Than Tobacco) in Tobacco Products

FDA Question
Provide studies or information regarding the role of flavors (other than tobacco) generally in tobacco products. If the response relies on research in other areas (e.g., consumer products), discuss the appropriateness of extrapolating from such research to tobacco products.

Flavors (Other Than Tobacco) and Initiation and Patterns of Tobacco Product Use, Particularly Among Youth and Young Adults

FDA Question
Provide studies or information regarding the role of flavors (other than tobacco) in initiation and/or patterns of use of combusted tobacco products, particularly among youth and young adults.

Provide studies or information regarding the role of flavors (other than tobacco) in initiation and/or patterns of use of noncombusted tobacco products, particularly among youth and young adults.

Provide studies or information regarding the role of flavors (other than tobacco) in noncombusted tobacco products on initiation of tobacco product use or progression to use of other tobacco products (for example, from noncombusted to combusted tobacco products), particularly among youth and young adults.

Flavors (Other Than Tobacco) and Cessation, Dual Use, and Relapse Among Current and Former Tobacco Product Users

FDA Question
Provide studies or information regarding the role of flavors (other than tobacco) in helping adult cigarette smokers reduce cigarette use and/or switch to potentially less harmful tobacco products.

Provide studies or information regarding the role of flavors (other than tobacco) in noncombusted tobacco products on the likelihood of: (1) cessation of combusted tobacco products use, (2) cessation of all tobacco product use, and (3) uptake of dual use of combusted and noncombusted tobacco products among current and former tobacco product users. Include information from, and define, all populations: youth, young adults, and adults (and any subgroup thereof, if applicable).
Provide studies or information regarding the role of flavors (other than tobacco) in noncombusted products on the likelihood of: (1) delayed or impeded cessation among users who would have otherwise quit combusted tobacco product use, or (2) delayed or impeded cessation among users who would have otherwise quit all tobacco product use. Include information from, and define, all populations: youth, young adults, and adults (and any subgroup thereof, if applicable).

Provide studies or information regarding the role of flavors (other than tobacco) in noncombusted tobacco products on the likelihood that former combusted tobacco product users relapse. Include information from, and define, all populations: youth, young adults, and adults (and any subgroup thereof, if applicable).

**Additional Public Health Considerations**

**FDA Question**

Provide studies or information regarding the potential toxicity or adverse health effects to the user or others from any flavors (e.g., flavor additives, compounds, or ingredients) in tobacco products. These adverse health outcomes may include, but are not limited to, cancer or adverse respiratory, cardiac, or reproductive/development effects. Of particular interest are studies or information on inhalation exposure to any flavor. Provide studies or information on what, if any, toxic chemicals might be formed from the heating or burning of tobacco products with flavors and the potential toxicity or health risks that might result from these formed chemicals.

Provide studies or information on the impact, whether intended or unintended, of public health efforts by local jurisdictions, States, and members of the international community to impose restrictions on the manufacture, marketing, sale or distribution of all or a subset of tobacco products with flavors (other than tobacco), including but not limited to cigars, ENDS, menthol cigarettes, and smokeless tobacco products.

Provide studies or information regarding consumer perceptions of the health risks of tobacco products with flavors (other than tobacco) when compared to other tobacco products, both with and without flavors. Include information from, and define, all populations: youth, young adults, and adults (and any subgroup thereof, if applicable).

Provide studies or information regarding consumer perceptions, if any, of the addictiveness of tobacco products with flavors (other than tobacco). Include information from, and define, all populations: youth, young adults, and adults (and any subgroup thereof, if applicable).
Tobacco Product Standards (All Flavors)

FDA Question
Are there any specific flavors for which FDA should establish a tobacco product standard? If so, which flavors (e.g., flavor additives, compounds, or ingredients) and why?

Our Take
Many cigarettes that are not marketed as menthol cigarettes include menthol as a flavor additive. Setting a limit on the amount of menthol in cigarettes would make all cigarettes less palatable, likely reducing initiation and increasing cessation.

FDA Question
With respect to your response to the previous question, what level (e.g., maximum, minimum, prohibition) should FDA establish to protect the public health, and why?

Our Take
The FDA has the authority to remove menthol and other flavor additives from cigarettes and other tobacco products.

FDA Question
If FDA were to establish a tobacco product standard prohibiting or restricting flavors, to which types of tobacco products should the standard apply (e.g., combusted, noncombusted, both), and why?

Our Take
The removal of flavors from all products would maximize the public health benefits. This is particularly true as the FDA moves forward with a nicotine standard for combustible products. There is no need to allow flavors in some products because the nicotine standard will create a greater incentive to switch to noncombustible products than the existence of flavors in those products.
Tobacco Product Standards (Menthol Flavor)

FDA Question
FDA has carefully reviewed the data it received in response to the 2013 ANPRM on menthol in cigarettes (78 FR 44484, July 24, 2013). Provide any additional data or information about the role of menthol in cigarettes, particularly regarding the role menthol plays in smoking initiation and in the likelihood of smoking cessation for all populations (youth, young adult, adult).

Our Take

The existing evidence base provides more than enough justification for the FDA to move forward with a prohibition on menthol.

FDA Question
What additional evidence exists on the likelihood that smokers would completely switch to another tobacco product, or start dual use with another product, in the event of a tobacco product standard prohibiting or limiting menthol in cigarettes?

What is the role, if any, that menthol plays in use of tobacco products other than cigarettes, including, but not limited to, cigars and ENDS?

Sale or Distribution Restrictions

FDA Question
FDA may consider restrictions on the sale and distribution of flavored tobacco products. Possible restrictions could include restrictions on the advertising and promotion of tobacco products with flavors; on access to tobacco products with flavors; and/or on the label, labeling, and/or packaging of tobacco products with flavors. These restrictions could include requirements to bear warnings or disclosure statements. What such restrictions, if any, should FDA consider and why?

Our Take

The best tool at the FDA’s disposal is a product standard that identifies flavor additives and prohibits them at any level. The FDA should also prohibit the sale of any tobacco product with a characterizing flavor. There’s no need for an either/or approach.
Other Actions and Considerations

FDA Question
To the extent that flavors may pose both (1) potential benefits to adult smokers who might consider switching to a noncombusted flavored tobacco product with lower individual risk and (2) potential risks to nonusers who might initiate use of tobacco products through flavored tobacco products or to current users who might progress to flavored tobacco products with higher individual risks, how should FDA assess and balance these benefits and risks?

Our Take

The potential benefit of keeping flavors in noncombusted products is nullified by a nicotine product standard for combusted products. The greater concern is the risk of youth initiation.

FDA Question
Provide studies or information on the role of tobacco flavor in tobacco products in initiation, patterns of use of tobacco products (particularly with respect to progression from non-combusted to combusted tobacco products or from combusted to non-combusted), reduction in use of combustible tobacco products and cessation of tobacco products. Include information from, and define, all populations: youth, young adults, and adults (and any subgroup thereof, if applicable).

Provide information on whether manufacturing process(es) affect product flavor. Describe any such manufacturing process(es), including the specific products that use the process(es), as well as specific flavors used in the process(es).

Provide analyses regarding any other tobacco product standard, regulatory action, or other action that FDA could implement that you believe would more effectively reduce the harms caused by flavors in tobacco products to better protect the public health than the tobacco product standards or other regulatory actions discussed in the preceding questions.

Discuss any other tobacco product standard, regulatory action, or other activity that FDA could pursue that would complement or increase the effectiveness of the potential tobacco product standards or other regulatory actions discussed in the preceding questions.

Are there any flavors that especially appeal to youth, young adults, or other specific age group? If so, how are such flavors distinguished from other flavors?
To the extent that you have identified a tobacco product standard or other regulatory action in response to the prior questions, provide additional information and comments on: (1) the technical achievability of compliance with the tobacco product standard or other regulatory action you identified; and (2) how FDA could maximize compliance and public health benefits.

If FDA were to establish a tobacco product standard prohibiting or restricting flavors in tobacco products, what evidence is there, if any, that consumers would start to flavor their own tobacco products?

What data may be used to assess and analyze the range and variety of flavored tobacco products that are currently available to consumers? How can available sources of information, such as manufacturer registrations and/or product listings with FDA, be used in this assessment?

Researchers 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.