



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1162 and 1166

[Docket Nos. FDA-2021-N-1349 and FDA-2021-N-1309]

Proposed Regulations to Establish Tobacco Product Standards for Menthol in Cigarettes and Characterizing Flavors in Cigars: Listening Sessions; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notification of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following virtual listening sessions entitled “Proposed Regulations to Establish Tobacco Product Standards for Menthol in Cigarettes and Characterizing Flavors in Cigars: Listening Sessions.”

The purpose of the listening sessions is to discuss two proposed regulations that are published elsewhere in this issue of the *Federal Register*, a tobacco product standard that would prohibit menthol as a characterizing flavor in cigarettes (“Tobacco Product Standard for Menthol in Cigarettes”; Docket No. FDA-2021-N-1349) and a tobacco product standard that would prohibit characterizing flavors (other than tobacco) in all cigars (“Tobacco Product Standard for Characterizing Flavors in Cigars”; Docket No. FDA-2021-N-1309). FDA will provide information on the proposed rules to the public and provide the public an opportunity to provide open public comment.

DATES: The listening sessions will be held on two separate days on June 13 and 15, 2022. All requests to make open public comment must be received by June 6, 2022, at 11:59 p.m. Eastern Time.

FDA reminds the public that, in addition to providing comments through these meetings, commenters may submit either electronic or written comments on one or both of the proposed rules set out in the SUMMARY by [INSERT DATE 60 DAYS AFTER DATE OF

PUBLICATION IN THE *FEDERAL REGISTER*]. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: Additional details, such as the time of the listening sessions and registration information, will be posted soon at <https://www.fda.gov/tobacco-products>. The listening sessions will be held virtually and more information will be posted here:

<https://www.fda.gov/tobacco-products>.

You may submit written comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2021-N-1349 for “Tobacco Product Standard for Menthol in Cigarettes” and/or Docket No. FDA-2021-N-1309 for “Tobacco Product Standard for Characterizing Flavors in Cigars.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit

both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the dockets to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: May Nelson, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 877-287-1373, CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Published elsewhere in this issue of the *Federal Register*, FDA is proposing two product standards: (1) a tobacco product standard that would prohibit menthol as a characterizing flavor in cigarettes (“Tobacco Product Standard for Menthol in Cigarettes”; Docket No. FDA-2021-N-1349) and (2) a tobacco product standard that would prohibit characterizing flavors (other than tobacco) in all cigars (“Tobacco Product Standard for Characterizing Flavors in Cigars”; Docket No. FDA-2021-N-1309). Characterizing flavors in tobacco products, including menthol, enhance taste and make them easier to use. Menthol’s flavor and sensory effects reduce the harshness of cigarette smoking and make it easier for new users, particularly youth and young

adults, to continue experimenting and progress to regular use. Characterizing flavors in cigars, such as strawberry, grape, cocoa, and fruit punch, increase appeal and make the cigars easier to use, particularly among youth and young adults. FDA is proposing these two tobacco product standards because they would significantly reduce disease and death from combusted tobacco product use, the leading cause of preventable death in the United States.

There are over 18.5 million menthol cigarette smokers ages 12 and older in the United States. The proposed “Tobacco Product Standard for Menthol in Cigarettes” rule would reduce the appeal of cigarettes, particularly to youth and young adults, and thereby decrease the likelihood that nonusers who would otherwise experiment with menthol cigarettes would progress to regular smoking. In addition, this proposed tobacco product standard would improve the health and reduce the mortality risk of current menthol cigarette smokers by decreasing cigarette consumption and increasing the likelihood of cessation.

Over a half million youth in the United States use flavored cigars. The proposed “Tobacco Product Standard for Characterizing Flavors in Cigars” rule would reduce the appeal of cigars, particularly to youth and young adults, and thereby decrease the likelihood of experimentation, development of nicotine dependence, and progression to regular use. This proposed standard also would improve public health by increasing the likelihood that existing users of flavored cigars would quit.

FDA is issuing both proposed product standards to reduce the tobacco-related death and disease associated with menthol cigarette and flavored cigar use. The proposed standards also are expected to reduce tobacco-related health disparities and advance health equity.

II. Topics for Discussion at the Listening Sessions

The listening sessions will provide the public an opportunity to provide open public comment on the proposed product standard rules. Both proposed rules will be discussed at each session. Although the public can submit their questions and comments directly to the dockets,

the listening sessions will enable FDA to share public information (i.e., what is contained in the rules and related documents) and facilitate comment on the proposed rules.

After introductions, FDA will begin each listening session with an overview of both proposed rules. Then the registered speakers will have approximately 5 minutes each to share their comments on any topics related to the product standards. FDA is particularly interested in the areas where we specifically requested comment in the proposed rules and the associated preliminary regulatory impact analyses.

III. Participating in the Listening Sessions

Registration: To register to attend the free listening sessions, please visit the following website: <https://www.fda.gov/tobacco-products>. Registration information will be posted soon.

Live closed captioning will be provided during the listening sessions. Additional information on requests for special accommodations due to a disability will be provided during registration.

Requests to Provide Open Public Comment: During online registration you may indicate if you wish to make open public comments during the listening sessions. All requests to make open public comment must be received by June 6, 2022, at 11:59 p.m. Eastern Time. We will do our best to accommodate requests to make public comments. We are seeking to have a broad representation of ideas and perspectives presented at the meeting. FDA is especially interested to hear from those individuals or communities who may be less likely or less able to provide formal written comments through the standard process of docket submission. Individuals and organizations with common interests are urged to consolidate or coordinate their comments and request time for a joint presentation. FDA will determine the approximate time open public comments are to be provided and will notify all registrants who requested to make public comment ahead of the listening session. FDA will not accept presentation materials for the listening sessions. Instead, any materials can be submitted to the respective docket noted in the “Docket” section of this document before the end of the comment period.

Transcripts: Please be advised that as soon as transcripts of the listening sessions are available, they will be accessible at <https://www.regulations.gov>. They may be viewed at the Dockets Management Staff (see ADDRESSES). A link to the transcripts and recordings will also be available on the internet at <https://www.fda.gov/tobacco-products>.

Dated: April 26, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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