



May 13, 2022

Dear Tribal Leader:

The U.S. Food and Drug Administration (FDA) is initiating consultation with federally recognized American Indian and Alaska Native tribes on two proposed rules: *Tobacco Product Standard for Menthol in Cigarettes* (Menthol proposed rule)<sup>1</sup> and *Tobacco Product Standard for Characterizing Flavors in Cigars* (Cigar Flavors proposed rule)<sup>2</sup>. These proposed rules published in the *Federal Register* on May 4, 2022. FDA is proposing to take these actions to reduce the tobacco-related death and disease associated with the use of these tobacco products. FDA's enforcement of these proposed rules would only address manufacturers, distributors, wholesalers, importers, and retailers. FDA does not regulate the use of traditional (ceremonial) tobacco, and the Agency respects the use of traditional tobacco by American Indian and Alaska Native tribes. Additional information about the proposed rules can be found in the attached fact sheet.

FDA invites you and/or your designated consultation representative(s) to participate in this consultation through an all tribes' call on **Wednesday, June 22, 2022, at 2:00 p.m. ET**. We will be hosting the 1-hour call to provide an overview of the proposed rules, answer questions, and receive tribal feedback. A transcript of the consultation will be added to the dockets for both rules and a recording of the consultation discussion will be available after the call.

**Tribal Consultation Call Information:**

**Wednesday, June 22, 2022, at 2:00 p.m. EDT**

**To participate in the call, you must register via the link [here](#).**<sup>3</sup>

In addition to the consultation call, there will be listening sessions on the proposed rules on June 13 and 15, 2022, and the Agency encourages tribal participation.<sup>4</sup> Additional details, such as the time of the listening sessions and registration information, will be posted soon at <http://www.fda.gov/Tobacco-Products>.

Also, FDA welcomes your written comments on the proposed rules. Comments on the Menthol proposed rule should be submitted to Docket No. FDA-2021-N-1349 and comments on the Cigar Flavors proposed rule should be submitted to Docket No. FDA-2021-N-1309. All comments

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<sup>1</sup> <https://www.federalregister.gov/documents/2022/05/04/2022-08994/tobacco-product-standard-for-menthol-in-cigarettes>.

<sup>2</sup> <https://www.federalregister.gov/documents/2022/05/04/2022-08993/tobacco-product-standard-for-characterizing-flavors-in-cigars>.

<sup>3</sup> <https://fda.zoomgov.com/meeting/register/vJItD-6gqzguGKnmKMUfNBSfptwo0kARok>

<sup>4</sup> See <https://www.federalregister.gov/documents/2022/05/04/2022-09302/proposed-regulations-to-establish-tobacco-product-standards-for-menthol-in-cigarettes-and>.

submitted by July 5, 2022, will be considered before the final rules are published. Comments must be submitted to FDA using any of the following methods:

- Electronic submissions: Follow the instructions for submitting comments on the Federal eRulemaking Portal at <http://www.regulations.gov>.
- Written submissions via Mail/Hand delivery/Courier: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Received comments will be placed in the docket and publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

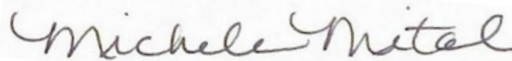
If you have any questions regarding the proposed rules, please contact David Oliveira at [CTP-TribalLiaison@fda.hhs.gov](mailto:CTP-TribalLiaison@fda.hhs.gov).

FDA's Intergovernmental Affairs (IGA) team is available to assist tribal officials for all FDA inquiries and can be reached via email at [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov). For more information regarding FDA's activities with federally recognized tribal governments, including FDA's Dear Tribal Leader Letters, please visit [www.fda.gov/tribal](http://www.fda.gov/tribal) or contact the IGA staff.

FDA encourages you to stay informed about further developments related to tobacco products through the CTP website located at <http://www.fda.gov/Tobacco-Products>, or by signing up for CTP email newsletters at <https://www.fda.gov/tobacco-products/ctp-newsroom/subscribe-fda-center-tobacco-products-ctp-email-newsletters>. You may also contact the Center via telephone at 1-877-CTP-1373, via email at [AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov), or via mail at 10903 New Hampshire Ave., Silver Spring, MD 20993.

I hope you can join us for the tribal consultation call on Wednesday, June 22, 2022. We look forward to continuing to strengthen the relationship between FDA and tribal governments as the Agency fulfills its mission to protect and promote public health.

Sincerely,



Michele Mital  
Acting Director, Center for Tobacco Products

Attachment: Fact Sheet

Tobacco Product Standard for Menthol in Cigarettes  
Docket No. FDA-2021-N-1349

The proposed rule, *Tobacco Product Standard for Menthol in Cigarettes*, published in the *Federal Register* on May 4, 2022 (87 FR 26454). The proposed rule, if finalized, would prohibit menthol as a characterizing flavor in cigarettes and cigarette components and parts, including those that are sold separately to consumers. Under the proposed rule, if finalized, no person may manufacture, distribute, sell, or offer for distribution or sale, within the United States a cigarette or cigarette component or part that is not in compliance with the product standard.

Menthol is a flavor compound added to cigarettes, which produces a minty taste and cooling sensation when inhaled. 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. In addition, data show that menthol cigarettes contribute to greater nicotine dependence in youth and young adults than non-menthol cigarettes. If finalized, the proposed 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, the proposed rule, if finalized, would improve the health and reduce the mortality risk of current menthol cigarette smokers by decreasing cigarette consumption and increasing the likelihood of cessation. Furthermore, the proposed rule, if finalized, is expected to substantially decrease tobacco-related health disparities and to advance health equity across populations groups.

Tobacco Product Standard for Characterizing Flavors in Cigars  
Docket No. FDA-2021-N-1309

The proposed rule, *Tobacco Product Standard for Characterizing Flavors in Cigars*, published in the *Federal Register* on May 4, 2022 (87 FR 26396). The proposed rule, if finalized, would prohibit characterizing flavors (other than tobacco) in all cigars and their components and parts. Under the proposed rule, if finalized, no person may manufacture, distribute, sell, or offer for distribution or sale, within the United States a cigar or any of its components or parts that is not in compliance with the product standard.

Characterizing flavors in cigars and other tobacco products play a key role in how users and nonusers, particularly youth, initiate, progress, and continue using tobacco products. Characterizing flavors in tobacco products increase the appeal of those tobacco products to youth and promote youth initiation, resulting in an increased likelihood that youth and young adults experimenting with flavored cigars will progress to regular cigar smoking. If finalized, the proposed rule would reduce the appeal of cigars, particularly to youth and young adults, and thus decrease the likelihood of experimentation, development of nicotine dependence, progression to regular use, and the resulting tobacco-related disease and death. The proposed rule, if finalized, also would improve public health by increasing the likelihood of cessation among existing cigar smokers. And it would improve health outcomes within groups that experience disproportionate levels of tobacco use, including certain vulnerable populations, thus advancing health equity.