



August 15, 2019

Dear Tribal Leader:

The U.S. Food and Drug Administration (FDA) is initiating consultation with federally recognized Indian tribes on the proposed rule, "Tobacco Products; Required Warnings for Cigarette Packages and Advertisements." The proposed rule will publish in the *Federal Register* on August 16, 2019, FR 17481. FDA is proposing to take this action to promote greater public understanding of the negative health consequences of cigarette smoking.

The proposed rule, once finalized, would implement a provision of the Family Smoking Prevention and Tobacco Control Act that requires FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany new textual warning statements on cigarette packages and advertisements. In accordance with this statutory mandate, the proposed rule, once finalized, would establish new required cigarette health warnings for cigarette packages and advertisements that would become effective 15 months after the issuance of the final rule. These new cigarette health warnings are proposed to consist of textual warning statements accompanied by color graphics, in the form of concordant photo-realistic images, depicting the negative health consequences of cigarette smoking.

In addition, the proposed rule, once finalized, would establish marketing requirements that would include the random and equal display and distribution of the required warnings for cigarette packages and quarterly rotations of the required warnings for cigarette advertisements. A tobacco product manufacturer or distributor, and any retailer responsible for cigarette advertising, would be required to submit a warning plan for the random and equal display and distribution of the required warnings on packages and the quarterly rotation in advertisements the manufacturer, distributor, or retailer is responsible for within 5 months of the issuance of the final rule for review and approval by FDA. The proposed rule, once finalized, would require each tobacco product manufacturer required to randomly and equally display and distribute required warnings on packaging or quarterly rotate required warnings on advertisements in accordance with an FDA-approved warning plan, to maintain a copy of the FDA-approved warning plan, and to make the warning plan available for inspection and copying by officers and employees of FDA.

FDA invites you and your designated consultation representative(s) to participate in an All Tribes' Call on September 19, 2019, at 1:00 p.m. EST. We will be hosting the call to provide an overview of the proposed rule, answer questions, and hear tribal comments on the proposed rule. A transcript of the consultation will be added to the docket for the proposed rule (Docket No. FDA-2019-N-3065). An instant replay of the All Tribes' Call will be available beginning approximately 1 hour after the call ends and will be available for 30 days.

All Tribes' Call Information:

Thursday, September 19, 2019, at 1:00 p.m. EST  
Toll-free number: 888-324-8573; Passcode: 4894721

Instant Reply Information:

Toll-free number: 800-839-5154

In addition, FDA welcomes your written comments on the proposed rule. All comments submitted to the docket by October 15, 2019, will be considered before the final rule is 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.

All comments must include the docket number for the proposed rule (Docket No. FDA-2019-N-3065). 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 rule or CTP's consultation activities with federally recognized Indian tribes, please contact David Oliveira at [CTP-TribalLiaison@fda.hhs.gov](mailto:CTP-TribalLiaison@fda.hhs.gov).

For more information on tribal consultation activities with FDA generally, please visit <http://www.fda.gov/federal-state-local-tribal-and-territorial-officials/tribal-affairs> or contact Nick Alexander, Director of Intergovernmental Affairs, at [nicholas.alexander@fda.hhs.gov](mailto:nicholas.alexander@fda.hhs.gov).

FDA encourages you to stay informed about further developments related to tobacco products through the Center for Tobacco Products website located at <http://www.fda.gov/TobaccoProducts>. 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.

Our mission at CTP is to make tobacco-related death and disease part of America's past, not America's future. By working together, we can promote healthier lives for your community.

I hope you can join us for the All Tribes' Call and I thank you for your interest in this important step toward improving public health.

Sincerely,



Mitchell Zeller  
Director, Center for Tobacco Products