DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

April 4, 2019

Dear Tribal Leader:

The U.S. Food and Drug Administration (FDA) is initiating consultation with federally recognized Indian tribes on the proposed rule, "Content and Format of Substantial Equivalence Applications; Food and Drug Administration Actions on Substantial Equivalence Reports." The proposed rule was published in the *Federal Register* on April 2, 2019, FR 12740.

The proposed substantial equivalence ("SE") rule would, if finalized, clarify when tobacco product manufacturers, including Tribal enterprises, may properly use the SE pathway to bring new tobacco products to market, the required content and format of SE Reports, and FDA's review process for SE Reports. For a product to be found substantially equivalent, it must either have the same characteristics as a predicate product or have different characteristics, but the different characteristics do not cause the new tobacco product to raise different questions of public health. The proposed rule describes the information an SE Report would have to include so that FDA could make an SE determination, and would help manufacturers seeking to receive marketing authorization for a tobacco product through the SE pathway to properly submit new tobacco product applications to FDA for SE review.

FDA invites you and your designated consultation representative(s) to participate in an All Tribes' Call on April 11, 2019 at 2:30 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-2016-N-3818). 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, April 11, 2019 at 2:30 p.m. EST
Toll-free number: 888-790-3721
Passcode: 6246107

Instant Replay Information:
Toll-free number: 888-568-0064

In addition, FDA welcomes your written comments on the proposed rule. All comments submitted to the docket by June 17, 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-2016-N-3818). 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.

For more information on tribal consultation activities with FDA generally, please contact Nick Alexander, Director of Intergovernmental Affairs, at 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, 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

Mitchell Zeller, J.D
Director, Center for Tobacco Products