DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

April 7, 2017

Dear Tribal Leader:

The U.S. Food and Drug Administration (FDA) is initiating consultation with federally recognized Indian tribes on the proposed rule, *Tobacco Product Standard for N-nitrosonornicotine Level in Finished Smokeless Tobacco Products*. On January 23, 2017, the proposed rule was published in the *Federal Register*, (82 FR 8004); a notice extending the comment period to July 10, 2017, and noting a correction in a certain formula was published in the *Federal Register* on March 22, 2017 (82 FR 14647).

Section 907 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to promulgate tobacco product standards that are appropriate for the protection of the public health, including provisions, where appropriate, for the reduction or elimination of constituents or harmful components of tobacco products (section 907(a)(4)(A)(ii) of the FD&C Act). With this rule, FDA is proposing a tobacco product standard that would establish a limit of N-nitrosonornicotine (NNN) in finished smokeless tobacco products sold in the United States.

FDA appreciates that the regulation of tobacco is of particular interest and an issue on which many have strong feelings. FDA welcomes your comments and input on the proposed rule, including whether the approach proposed in the proposed rule is appropriate. All comments submitted to the docket by July 10, 2017, 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-2527). Received comments will be placed in the docket and publicly viewable at http://www.regulations.gov, or at the Division of Dockets Management between 9:00 a.m. and 4:00 p.m., Monday through Friday.

If you have any questions regarding the proposed rule or CTP's consultation activities with federally recognized tribal governments, please contact Paul Allis at CTP-TribalLiaison@fda.hhs.gov.

Additional information regarding FDA's regulation of tobacco products can be found on 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.

The FDA looks forward to continuing to work with Tribal Leaders as the Agency fulfills its mission to protect and promote public health.

Sincerely,

Mitchell Zeller

Mitchell Zeller
Director, Center for Tobacco Products