DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

May 10, 2016

Dear Tribal Leader:

The U.S. Food and Drug Administration (FDA) is announcing a final rule entitled, "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products" ("deeming rule"). The final rule was published in the *Federal Register* on May 10, 2016, 81 FR 28973.

This rule was proposed on April 25, 2014 (79 FR 23141). FDA informed and sought comment from Tribal Governments on April 25, 2014, in a Dear Tribal Leader Letter, and conducted a consultation with tribes via Webinar regarding the proposed rule on May 29, 2014. FDA also responded to requests from individual tribes for consultation. FDA received more than 135,000 comments from the public on the proposed rule, including comments from Tribes and tribal entities. FDA carefully considered all of the comments.

The final rule, among other things:

- Extends FDA's "tobacco product" authorities to all other categories of tobacco products meeting the statutory definition of "tobacco product" in the Federal Food, Drug and Cosmetic Act, except accessories of such products;
- Prohibits the sale of "covered tobacco products" to individuals under the age of 18;
- Prohibits vending machine sales (except in facilities that prohibit individuals under the age of 18 years from entering at any time); and
- Requires the display of health warnings on "covered tobacco products," cigarette tobacco, and roll-your-own tobacco (RYO tobacco) packages and advertisements.

"Covered tobacco products" are all deemed products except components or parts that are not made or derived from tobacco. These newly regulated products include currently marketed products, such as electronic cigarettes, cigars, pipe tobacco, and waterpipe (hookah) tobacco, and future tobacco products.

These federal requirements apply to all enterprises that manufacture, market, or distribute regulated tobacco products, including Tribally-owned and operated enterprises and enterprises located on Tribal lands.

A more detailed summary of the final rule is attached.

The final deeming rule will afford FDA additional tools to reduce the number of illnesses and premature deaths associated with tobacco product use. These actions will improve the public health by:

1. Affording FDA the opportunity to obtain critical information regarding the health risks of such products;
2. Preventing new tobacco products from entering the market unless such products are shown to be appropriate for the protection of public health, substantially equivalent to a valid predicate product, or are exempted from the substantial equivalence requirements; and
3. Preventing the marketing of modified risk tobacco products, which may be marketed with unsubstantiated claims and may mislead consumers to initiate tobacco product use or to continue using tobacco when they would otherwise quit, without an FDA order.

FDA is also announcing a compliance policy for small-scale tobacco product manufacturers, offering them targeted relief to address concerns that small manufacturers may need additional time to comply with certain requirements of the deeming rule. This compliance policy will apply to small-scale tobacco product manufacturers (i.e., those manufacturers with 150 employees or fewer and less than $5,000,000 in annual revenues). Interested tribal manufacturers can find more information by contacting CTP's call center at 1-877-CTP-1373.

Lastly, FDA has made available a draft guidance for Electronic Nicotine Delivery Systems (ENDS) premarket tobacco product applications which, when final, will describe FDA's current thinking regarding ways of addressing the premarket authorization requirements for newly deemed ENDS products. FDA has also made available a final guidance to provide information on how to establish and reference a Tobacco Product Master File (TPMF). In addition, FDA is issuing a final rule regarding user fees for cigars and pipe tobacco, including the submission of information needed to calculate user fee assessments in the *Federal Register*, 81 FR 28707.

The final deeming rule will be effective 90 days after publication. We will work with Tribes to provide education and technical assistance to help you comply with the requirements. FDA encourages you to stay informed about further developments related to tobacco products through the Center for Tobacco Products website located at: www.fda.gov/TobaccoProducts.

If you have any questions please contact:

Paul Allis
Policy Analyst, Tribal Affairs
Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993
Paul.Allis@fda.hhs.gov

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.

FDA is committed to a government-to-government relationship and plans to keep Tribes informed and provide information, as available, about the FDA deeming rule and new

regulations. 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 thank you for your interest in this important step toward improving public health.

Sincerely,

Mitchell Zeller

Mitchell Zeller
Director, Center for Tobacco Products