DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
9200 Corporate Boulevard
Rockville MD 20850-3229

April 25, 2014

Dear Tribal Leader:

On Thursday, May 29, 2014, the U.S. Food and Drug Administration (FDA) will host a Tribal Consultation via webinar from 2:00 pm to 4:00 pm EDT to discuss FDA's proposed rule entitled "Deeming Tobacco Products To Be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products." The proposed rule was published in the *Federal Register* on April 25, 2014, 79 FR 23141, and a summary of this proposed rule is included in the attached fact sheet.

The purpose of the proposed rule is to address the public health concerns associated with the use of tobacco products. Tobacco use causes many diseases, including heart disease, diabetes, and cancer.[1] These are major causes of death among American Indians and Alaska Natives.[2] The act of deeming additional tobacco products to be subject to FDA's jurisdiction would result in significant benefits for the public health by affording FDA additional tools to use to reduce the number of illnesses and premature deaths associated with the use of tobacco products.

As described in the attached fact sheet, the proposed "deeming rule" would, if finalized, automatically subject additional tobacco products to FDA's tobacco product authorities. This would enable FDA to issue future science-based regulations to address newly deemed products and further reduce the death and disease associated with tobacco use. This will help improve, over time, the health of the members of American Indian and Alaska Native Tribes. Additionally, the proposed rule contains youth access restrictions that, if finalized, would prohibit the sale of all newly deemed products to youth. Any owners of enterprises that manufacture, market, or distribute regulated tobacco products, including Tribal enterprises or enterprises located on Tribal lands, would be required to comply with these requirements.

Because of the potential impact on federally recognized Tribes, FDA invites Tribal leaders to participate in a Tribal Consultation via webinar to discuss the proposed rule. The webinar will provide information on the proposed rule and an opportunity for participants to provide feedback and ask questions.

Participants are encouraged to register for the webinar prior to the event by providing your name and tribal affiliation via email at CTP-TribalConsult@fda.hhs.gov or by phone at 301-796-6827. Participants who wish to submit questions prior to the webinar can send them via email to CTP-TribalConsult@fda.hhs.gov. A transcript of the consultation will be added to the official docket. FDA also encourages Tribal leaders and potentially affected stakeholders to review the proposed

[1] 2014 Surgeon General's Report: The Health Consequences of Smoking – 50 Years of Progress (http://www.cdc.gov/tobacco/data_statistics/sgr/50th-anniversary/index.htm)
[2] NCHS, NVSS, V60, N3, Dec.29, 2011, Deaths, Final Data for 2009 (http://www.cdc.gov/nchs/data/nvsr/nvsr60/nvsr60_03.pdf)

rule and submit comments to the official docket if they have concerns or data that should be considered. All comments submitted to the official docket will be considered before the final rule is published. Instructions for joining the webinar and submitting a comment to the docket are provided below.

Webinar instructions:
To join via internet:

- Go to the Center for Tobacco Products website at www.fda.gov/tobacco and type "Tribal and Territorial Governments" in the search bar. A link to the webinar will be available on the "State, Local, Tribal, and Territorial Governments" webpage on the day of the event.
- You may also link directly to this page using the following link: http://www.fda.gov/TobaccoProducts/ResourcesforYou/StateLocalTribalandTerritorialGovernments/default.htm
- You may listen to the webinar through your computer's speakers or by dialing in using the telephone access information below. Closed captioning will be available.

Telephone Access:

- To listen to the audio of the webinar on the day of the event dial 1-866-901-3913, passcode is 60985.

Webinar Replay:

- A link to the replay of the webinar will be available on the same webpage approximately 24 hours after the event.

If you have any questions regarding the webinar, please call 301-796-6827.

Submitting Comments

If you have comments on the proposed rule, you must submit them to Docket No. FDA-2014-N-0189 by July 9, 2014, 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

  - FAX: 301-827-6870.
  - Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions) to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

All submissions received must include the Agency name, Docket No., and Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided.

For access to the docket to read background documents or comments received, go to http://www.regulations.gov and insert the docket number into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

If you have any questions regarding the proposed rule, please contact Gerie Voss, Office of Regulations, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229, 877-287-1373, CTPRegulations@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/default.htm. You may also contact the Center via telephone at 1-877-CTP-1373, via email at AskCTP@fda.hhs.gov, or via mail at 9200 Corporate Boulevard, Rockville, MD 20850.

I hope you are able to join us for this Tribal Consultation via webinar 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