March 10, 2023

Dear Tribal Leader:

The U.S. Food and Drug Administration (FDA) respects tribal sovereignty and honors the Nation-to-Nation relationship it has with federally recognized American Indian and Alaska Native (AI/AN) tribes and continues to value your input in our decision making. FDA does not regulate the use of traditional (ceremonial) tobacco, and the Agency respects the use of traditional tobacco by AI/AN tribes.

FDA is initiating consultation with federally recognized AI/AN tribes on the proposed rule: *Requirements for Tobacco Product Manufacturing Practice* (TPMP proposed rule).[1] This proposed regulation would apply to manufacturers (foreign and domestic) of finished and bulk tobacco products and set forth requirements for the manufacture, preproduction design validation, packing, and storage of finished and bulk tobacco products. FDA is proposing this action to help assure that the public health is protected and that tobacco products are in compliance with chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act) by, among other things, minimizing the likelihood of the manufacture and distribution of contaminated or otherwise nonconforming tobacco products. Additional information about the proposed rule can be found in the attached fact sheet.

FDA invites you and/or your designated consultation representative(s) to participate in this consultation through an all tribes' call on April 11, 2023. FDA will be hosting the call to provide an overview of the proposed rule, answer questions, and receive tribal feedback. A transcript of the consultation will be added to the docket for the proposed rule. A recording of the consultation call will be available on the FDA Tribal Affairs webpage.[2] Additionally, a transcript of the call will be sent to those that attended the consultation.

Tribal Consultation Call Information:
April 11, 2023 at 2:00 p.m. EDT
To participate in the call, you must register via the link here.[3]

In addition to the consultation call, there will be a Part 15 meeting[4] on April 12, 2023, and Tobacco Product Scientific Advisory Committee[5] on May 18, 2023, and the Agency encourages

[1] *See* 88 FR 15174 (https://www.federalregister.gov/documents/2023/03/10/2023-04591/requirements-for-tobacco-product-manufacturing-practice)
[2] https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/tribal-affairs.
[3] https://fda.zoomgov.com/meeting/register/vJItdOqvrD8iGK2CBNgh0JiCrptHPkN3_-k.
[4] https://www.fda.gov/tobacco-products/ctp-newsroom/fdas-proposed-new-requirements-tobacco-product-manufacturing-practices-04122023.
[5] https://www.fda.gov/advisory-committees/committees-and-meeting-materials/tobacco-products-scientific-advisory-committee.

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tribal participation. Additional details, such as the time of the meetings and registration information, will be posted at http://www.fda.gov/Tobacco-Products.

Also, FDA welcomes your written comments on the proposed rule. Comments on the TPMP proposed rule should be submitted to Docket No. 2013-N-0227.[6] All comments submitted by September 6, 2023, 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.

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.

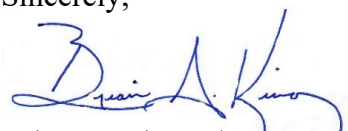
If you have any questions regarding the proposed rule, please contact David Oliveira at CTP-TribalLiaison@fda.hhs.gov.

FDA's IGA team is available to assist tribal officials for all FDA inquiries and can be reached at IGA@fda.hhs.gov. For more information regarding FDA's activities with federally recognized tribal governments, including FDA's Dear Tribal Leader Letters, please visit www.fda.gov/tribal or contact the IGA staff.

FDA encourages you to stay informed about further developments related to tobacco products through the CTP website located at http://www.fda.gov/TobaccoProducts or by signing up for CTP email newsletters at https://www.fda.gov/tobacco-products/ctp-newsroom/subscribe-fda-center-tobacco-products-ctp-email-newsletters. 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.

I hope you can join us for the tribal consultation call on April 11, 2023. FDA looks forward to continuing to strengthen the relationship between FDA and tribal governments as the Agency fulfills its mission to protect and promote public health.

Sincerely,



Brian A. King, PhD, MPH
Director, Center for Tobacco Products

Attachment: Fact Sheet

[6] http://www.regulations.gov/docket/FDA-2013-N-0227.

Requirements for Tobacco Product Manufacturing Practice
Docket No. FDA 2013-N-0227

The proposed rule, "Requirements for Tobacco Product Manufacturing Practice" published in the Federal Register on March 10, 2023. The proposed rule, if finalized, would set forth the requirements with which finished and bulk tobacco product manufacturers must comply in the manufacture, preproduction design validation, packing, and storage of finished and bulk tobacco products, to assure that the public health is protected and that tobacco products are in compliance with chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The proposed rule sets forth requirements for tobacco product manufacturing practice (TPMP) and provides a framework for manufacturers of finished or bulk tobacco products to follow that would include: (1) establishing tobacco product design and development controls to prevent or minimize certain risks; (2) ensuring that finished and bulk tobacco products are manufactured in conformance with established specifications; (3) minimizing the likelihood of the manufacture and distribution of nonconforming tobacco products; (4) requiring investigation and identification of nonconforming products, including those that have been distributed in order to institute appropriate corrective actions, such as conducting a recall as needed; (5) requiring manufacturers to take appropriate measures to prevent contamination of tobacco products; and (6) establishing traceability to account for all components or parts, ingredients, additives, and materials, as well as each batch of finished or bulk tobacco product, to aid in investigations of nonconforming tobacco products. Therefore, this proposed regulation would establish requirements for the control of tobacco product manufacturing activities and the treatment of contaminated or otherwise nonconforming tobacco products, including the investigation, evaluation, and corrective and preventive actions necessary to protect the public health.