FDA Tribal Consultation on the Proposed Rule *"Requirements for Tobacco Product Manufacturing"*

Background

On March 10, 2023, FDA published in the Federal Register, a proposed rule *Requirements for Tobacco Product Manufacturing Practice* (TPMP proposed rule). FDA is seeking stakeholder comments. Tribal officials have been given the opportunity to provide their recommendations and feedback. Tribal officials were invited to attend a virtual tribal consultation session with FDA which was held on April 11, 2023. Tribal officials also may provide written feedback to FDA through the docket Docket No. 2013-N-0227 by September 6, 2023. These opportunities to provide feedback were announced in an FDA Dear Tribal Leader Letter dated March 10, 2023.

Summary

The proposed rule, *Requirements for Tobacco Product Manufacturing Practice (TPMP)*, would 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.

There were 19 registrants, including Tribal officials, Tribal community members, Tribal public health representatives, and federal FDA participants for the virtual Tribal consultation. Paul Allis, Senior Intergovernmental Affairs Specialist opened the Tribal consultation with a welcome and announcements regarding the consultation proceedings and meeting expectations. He then discussed the unique government-to-government relationship that federally recognized tribes have with the federal government and reaffirmed FDA's commitment to robust and meaningful consultation with Tribes. Mr. Allis introduced Dr. Brian King, Director, Center for Tobacco Products (CTP) who provided an overview and importance of modernizing the FDA's oversight of clinical research and harmonization with other HHS regulations. Next, Matthew Brenner, Sr. Regulatory Counsel, Office of Regulations (OR) defined key terminology and provided an detailed account of the requirements regarding the manufacture, design, packing, and storage of their tobacco products.

Following FDA's presentation, there was a question and answer session. Paul Allis, FDA Intergovernmental Affairs, read through anticipated questions to further the exchange and to provide clarity on requirements of the proposed rule. There were no additional questions posed by attendees. Questions were answered in detail by CTP subject matter experts, Emil Wang, Office of Compliance and Enforcement and Matthew Brenner, Office of Regulation (OR) The questions posed were as follows:

1. If as a nation we do not manufacture tobacco, does this rule affect us in any way? We do sell tobacco products. Does it affect sellers?
2. Does this affect use of ceremonial tobacco at all?
3. Will there be exemptions from the requirements for manufacturers?
4. Do these requirements create undue burden on tobacco product manufacturers?
5. What actions will FDA take if a manufacturer is not meeting the requirements? Will FDA first issue a Warning Letter? Are there potential financial penalties?

There were no additional questions and the Tribal consultation was concluded.

Next Steps

FDA subsequently posted a recording of the tribal consultation on our website and shared it with registrants. FDA will post a copy of the tribal consultation transcript to the docket. FDA is accepting comments to the docket through September 6, 2023 and will continue to monitor the docket for additional comments from Tribal officials.