



Summary: FDA All Tribes Call on “*Establishment Registration and Product Listing for Tobacco*” Proposed Rule

Background

The U.S. Food and Drug Administration (FDA) convened a tribal consultation call to discuss the agency's proposed rule: [*“Establishment Registration and Product Listing for Tobacco Products”*](#) (R&L proposed rule) published in the Federal Register on June 29, 2026. The session was facilitated by Dr. Paul Allis, Senior Intergovernmental Affairs Specialist in the Office of Policy, Legislation and International Affairs. Nicholas Alexander, JD, who leads FDA's Intergovernmental Affairs (IGA) team, reaffirmed the agency's commitment to meaningful, sustained, and responsive tribal engagement and noted that the IGA team serves as FDA's primary liaison to tribal governments.

Dr. Bret Koplow, Acting Director of FDA's Center for Tobacco Products (CTP), underscored that FDA's regulatory authority applies exclusively to commercial tobacco and not to the sacred and traditional use of tobacco by American Indian and Alaska Native (AI/AN) communities, which FDA does not regulate. Dr. Koplow noted that commercial tobacco causes more than 490,000 deaths annually in the United States and that AI/AN adults were 60% more likely than the overall U.S. adult population to be current cigarette smokers as of 2024.

The proposed rule was framed as a critical step toward closing a longstanding regulatory gap, as domestic tobacco product manufacturers, including tribally owned businesses, are already required by federal law to register their establishments and list their products with FDA, while foreign manufacturers are not subject to these same requirements absent a regulatory mandate.

Summary

The consultation included a presentation by James Anthony, Regulatory Counsel with CTP's Office of Regulations, and Anthony Villa, JD, Senior Regulatory Counsel with CTP's Office of Compliance and Enforcement, followed by a Q&A session. The presentation clarified that the proposed rule would not change the fundamental registration and listing obligations already applicable to tribal manufacturers, who would continue to update their establishment registrations annually by December 31 and their product listings twice yearly in June and December. The rule would streamline the process by clarifying required versus voluntary information, allowing registrants to confirm no changes rather than resubmitting unchanged information, and formalizing electronic submission through the [*Tobacco Registration and Listing Module Next Generation \(TRLM Next Gen\)*](#). A waiver process would be available for those without email access, a computer, or internet service, with technical assistance available to tribes as needed. The presentation also highlighted that the proposed rule includes a provision that is directly relevant to tribal manufacturers. If an establishment is located in Indian Country, registrants would be asked



to provide the name of the Tribe as part of establishment registration. This information would help FDA coordinate compliance directly with the appropriate tribal government, and it respects the statutory limits on contracting with third parties for inspections in Indian Country.

The Q&A session addressed four key aspects of the proposed rule:

- **Applicability to Retailers:** The proposed rule would apply to owners and operators of domestic and foreign establishments engaged in the manufacturing, preparation, compounding, or processing of a tobacco product, including repackaging or relabeling of any tobacco product. The proposed rule would not apply if the individual or entity does not meet the definition of a tobacco product manufacturer. Retailers that do not manufacture their own tobacco products, like e-liquids, are outside the scope of the proposed rule.
- **Exemptions from Registration and Listing Requirements:** The proposed rule does not include exemptions. However, the proposed rule specifies who would not be required to register and list, including manufacturers of investigational use tobacco products not available for sale or distribution, manufacturers of raw materials other than tobacco, common carriers acting in the usual course of business, and establishments that exclusively manufacture tobacco products that enter a foreign trade zone and are exported from that foreign trade zone without being further distributed in the U.S.
- **FDA Actions for Non-Compliance:** Generally, for failure to comply with registration and listing requirements, FDA would typically first issue a warning letter in an attempt to achieve compliance with the law. If there is continued non-compliance, FDA may initiate further action as appropriate, such as seizure, injunction, or refusal of import.
- **Public Disclosure of Registration and Listing Information:** Registration and listing information would be posted to FDA's website with the agency carefully balancing transparency goals against protections for confidential commercial information.

Next Steps

The public comment docket will remain open until September 14, 2026. All comments must be submitted to [Docket No. FDA-2025-N-7130](#). The docket link is available on FDA.gov. Follow-up materials, including a link to the session recording, will be distributed to registrants and posted to the [FDA Tribal Affairs webpage](#). Participants with additional questions were encouraged to contact Dr. Allis directly or reach the IGA team at IGA@fda.hhs.gov.