June 30, 2026

Dear Tribal Leader:

The U.S. Food and Drug Administration (FDA or the Agency) is initiating consultation with federally recognized American Indian and Alaskan Native (AI/AN) tribes on the proposed rule: "*Establishment Registration and Product Listing for Tobacco Products*" (R&L proposed rule).[1] This proposed regulation would prescribe the format, content, and procedures for establishment registration and tobacco product listing. Complete and accurate establishment registration and product listing information is important to accomplish statutory, regulatory, and public health objectives.

Currently, in accordance with section 905 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), only domestic owners and operators, including Tribal owners and operators, are required to register their establishments and list their tobacco products with FDA while foreign owners and operators are not subject to these requirements. This action, if finalized, would extend registration and listing requirements to owners and operators of foreign establishments. For domestic owners and operators currently required to register and list, the proposed regulation would streamline the registration and listing process. Additional information about the proposed rule can be found in the attached fact sheet. FDA does not regulate individual consumer use, including the use of traditional (ceremonial) tobacco, and the Agency respects the use of traditional tobacco by AI/AN tribes.

FDA respects Tribal sovereignty and honors the Nation-to-Nation relationship it has with federally recognized AI/AN tribes and continues to value your input in our decision making. FDA invites you and/or your designated representative(s) to participate in this consultation through an all Tribes' call on **Thursday, July 30, 2026 at 1:00 p.m. EDT**. 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 who attend the consultation.

Tribal Consultation Call Information:
Thursday, July 30, 2026 at 1:00 p.m. EDT
To participate in the call, you must register via the link here.[3]

Also, FDA welcomes your comments on the proposed rule, which must be submitted to Docket

[1] *See* 91 FR 39168 (https://www.federalregister.gov/documents/2026/06/29/2026-13047/establishment-registration-and-product-listing-for-tobacco-products).
[2] https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/tribal-affairs.
[3] https://events.gcc.teams.microsoft.com/event/a8fe0573-feca-4b87-8dd6-3fbb39fb52ba@7d2fdb41-339c-4257-87f2-a665730b31fc.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

No. FDA-2025-N-7130[4]. All comments submitted by September 14, 2026, will be considered before the final rule is published. Comments must be submitted to FDA using either 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: Dockets Management Staff (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 Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

FDA's Intergovernmental Affairs (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 following methods:

- Visiting the Center for Tobacco Products' (CTP) website located at http://www.fda.gov/TobaccoProducts;
- Signing up for CTP email newsletters at https://www.fda.gov/tobacco-products/ctp-newsroom/subscribe-fda-center-tobacco-products-ctp-email-newsletters; or
- Contacting CTP
    - Via telephone at 1-877-CTP-1373;
    - Via email at AskCTP@fda.hhs.gov; or
    - Via mail at Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Avenue, Building 71, Room G335, Silver Spring, MD 20993-0002.

I hope you can join us for the tribal consultation call on Thursday, July 30, 2026. We look 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,



Bret Koplow, Ph.D., J.D.
Acting Director, Center for Tobacco Products

Attachment: Fact Sheet

[4] https://www.regulations.gov/docket/FDA-2025-N-7130.

Establishment Registration and Product Listing for Tobacco Products
Docket No. FDA-2025-N-7130

The proposed rule, "Establishment Registration and Product Listing for Tobacco Products" published in the *Federal Register* on June 29, 2026. Domestic manufacturers of tobacco products are currently required by law to register their establishments and list their tobacco products, while foreign manufacturers are not. If finalized, this rule would apply registration and listing requirements to both domestic and foreign manufacturers of tobacco products.

Who Must Register and List

- Domestic and foreign establishments that manufacture, prepare, compound, or process tobacco products that are subject to chapter IX of the FD&C Act.[5] This proposed rule clarifies that persons who engage in the manufacture of a tobacco product include specification developers, third-party manufacturers, and bulk tobacco product manufacturers.

What Information Will Be Required

The proposed rule describes when and how registrants would be required to register and list and the type of information that would be required, including:

- Establishment registration information
- Tobacco product listing details
- Historical files containing:
    - Consumer information
    - Product labeling
    - Advertisements for all listed tobacco products
    - Information related to distribution of free samples of smokeless tobacco products

The proposed rule streamlines the registration and listing process by enabling registrants to complete updates more efficiently, specifying the uniquely identifying information for establishments and listed products, and designating which information is required or voluntary.

Why This Rule Is Needed

- The information required by this rule would help FDA identify tobacco products sold, distributed, and/or imported into the United States, and the establishments that manufacture them, that do not comply with federal law. In addition, the information required by this rule would help FDA better pursue enforcement actions against non-compliant or illicit tobacco products that await or enter commercial distribution in the United States.

[5] The proposed rule would thus not apply to "premium cigars" that are not subject to chapter IX of the FD&C Act.