November 8, 2022

Dear Tribal Leader:

The U.S. Food and Drug Administration's (FDA or Agency), Center for Tobacco Products (CTP), regulates the manufacturing, marketing, and distribution of all commercial tobacco products, including cigarettes, smokeless tobacco, e-cigarettes, and cigars. Please note that FDA does not regulate the use of traditional (ceremonial) tobacco. FDA understands and respects the use of traditional tobacco by some American Indian and Alaska Native (AI/AN) tribes.

We recognize and appreciate the efforts tribal governments and health officials have actively taken to reduce commercial tobacco use in your communities, especially among tribal youth. FDA respects tribal sovereignty and honors the Nation-to-Nation relationship it has with federally recognized AI/AN tribes.

Recently, a growing number of companies, including manufacturers of some of the e-cigarette brands most popular with youth, began using non-tobacco nicotine (NTN), such as synthetic nicotine, to manufacture their products. We are writing to you to inform you that an important new federal law went into effect clarifying FDA's authority to regulate tobacco products containing NTN.

As of April 14, 2022, when the law went into effect, manufacturers, distributers, importers, and retailers of NTN products must ensure they are in compliance with applicable requirements of the law, such as the prohibition against selling these products to persons under 21 years of age (both in-person and online) and distributing free samples of these products.

After July 13, 2022, an NTN product can only be legally marketed in the United States if it has received premarket authorization from FDA. This means that it is illegal for a retailer or distributor to sell or distribute an NTN product that is not subject to a marketing granted order (MGO) from FDA. Without an MGO from FDA, a product is in violation of the law and a retailer or distributor that continues to sell or distribute the product may be subject to FDA enforcement. To date, no NTN product has received an MGO.

Retailers should discuss with their suppliers about the status of any tobacco product's premarket application or marketing authorization. FDA also maintains a list of MGOs and marketing denial orders (MDOs), with each order identified by manufacturer and product name, available on FDA's Tobacco Products Marketing Orders. Please note that FDA's list of MDOs includes only those products that FDA or the manufacturer confirmed to be currently marketed at the time the premarket application was submitted.

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In addition to notifying you of this important update to the law, we are also writing to invite you to partner with FDA to help protect the youth in your community from death and disease caused by commercial tobacco use and to help build a healthier community by ensuring retailers comply with FDA's tobacco laws and related regulations. FDA contracts with states, U.S. territories, and AI/AN tribes to conduct inspections, also called compliance checks, of tobacco retailers throughout the United States to determine retailer compliance. FDA currently utilizes its own inspectors to conduct retailer inspections on AI/AN lands where FDA does not have contracts with the tribe.

We encourage Tribes and tribal health officials to partner with FDA to conduct these inspections. By working together, we can have healthier lives and communities. We welcome the opportunity to meet with you to discuss the FDA Tobacco Retail Inspection Program and answer any questions you may have. Through a collaborative partnership, we can protect the health of AI/AN communities, especially youth, by ensuring compliance with FDA's tobacco laws and related regulations.

You can learn more about CTP by visiting our website at https://www.fda.gov/about-fda/fda-organization/center-tobacco-products and https://www.fda.gov/tobacco-products/compliance-enforcement-training/state-local-tribal-and-territorial-governments. For more information regarding FDA's activities with federally recognized tribal governments, including FDA Dear Tribal Leader Letters, please visit www.fda.gov/tribal.

If you have specific questions about our program and would like to discuss how we can partner to conduct inspections at tobacco retail establishments, please contact CTP's Thomas Lawson (thomas.lawson@fda.hhs.gov or 240-402-4254).

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

We look forward to continuing to strengthen the relationship between FDA and tribal governments and to working with you to protect and advance public health.

Sincerely,

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