



May 16, 2014

Dear Tribal Leader:

The U.S. Food and Drug Administration (FDA or the Agency) is committed to meaningful consultation with federally recognized Tribes on FDA's implementation and enforcement of the Family Smoking and Tobacco Control Act (Tobacco Control Act), a public health law designed to reduce the death and disease caused by tobacco.

On June 16, 2014, from 2:00 – 4:00 p.m. (EDT), the Agency will hold a consultation webinar to provide information on compliance and enforcement of the Tobacco Control Act in Indian Country. This webinar is important because it will go over provisions of the law related to tobacco retailers and manufacturers that may affect you and your Tribe. This is an opportunity for participants to provide feedback and ask questions. **You can join this consultation webinar by using the following link: <http://bit.ly/ctpwebinar>.**

FDA respects Tribal sovereignty and honors the government-to-government relationship it has with Tribes. We understand and respect that there are traditional uses of tobacco among the Tribes, and this Act only applies to the manufacturing, sale, and marketing of regulated tobacco products, with a primary goal of protecting public health. The Tobacco Control Act also authorizes FDA to contract with Tribal governments, where feasible, to assist FDA in conducting inspections of tribal tobacco retailers.

Partnering with Tribes on Retailer Compliance. Retailers play a role in protecting the health of America's youth by not selling, marketing, or advertising cigarettes or smokeless tobacco products to underage children and adolescents. FDA conducts compliance check inspections of tobacco product retailers to determine a retailer's compliance with federal laws and regulations and generally issues Warning Letters for first-time violations. Also, FDA generally issues civil money penalties for violations found on subsequent inspections.

FDA seeks to partner with your Tribe to both educate retailers that operate under your jurisdiction about the requirements under the law and to assist FDA in enforcing the retail requirements under the Tobacco Control Act. Through this partnership, we can help ensure youth are protected from marketing and tobacco sales violations that place them at risk. FDA plans to contract with Tribes, much like it contracts with states and territories, to work with us in a collaborative approach to enforcement. We will keep you informed of contracting opportunities as they become available. You can also check our State, Local, Tribal, Territorial website for more information (provided below).

Manufacturing Inspections. The Tobacco Control Act also impacts regulated tobacco manufacturers. Every person or company that owns or operates any domestic establishment engaged in the manufacture, preparation, compounding, or processing of a regulated tobacco product must register those establishments with FDA and list their products with the Agency. FDA conducts inspections of registered manufacturers, to ensure compliance with applicable provisions of the Food, Drug & Cosmetic Act and its implementing regulations. Provisions

covered in the inspections include, but are not limited to, establishment registration and product listing; ingredient listing; packaging, labeling, and advertising requirements; and marketing authorization for new and modified risk tobacco products. Some Tribally affiliated manufacturers have complied with some of these provisions. Every registered manufacturer is subject to biennial inspections, including those in Indian Country.

More information about FDA's inspections of regulated tobacco manufacturers is included in a webinar recorded on January 17, 2012, and can be found at:

<http://www.fda.gov/TobaccoProducts/ResourcesforYou/ucm288657.htm>

More information. We have enclosed additional information about the Tobacco Control Act for your reference. You can also learn more about CTP, the Tobacco Control Act, compliance and enforcement efforts, public education efforts, and other information by visiting our website at www.fda.gov/Tobacco. We encourage you to participate in upcoming webinars and other opportunities for public participation. Please check the web site for new and upcoming Dear Tribal Leader Letters, upcoming consultations, and other information for Tribes, which can be found at our "State, Local, Tribal, and Territorial" webpage:

<http://www.fda.gov/TobaccoProducts/ResourcesforYou/StateLocalTribalandTerritorialGovernments/default.htm>.

For general questions about CTP's retail compliance check inspections or registering for the June 16, 2014 webinar, contact: Evonne Bennett-Barnes, Tribal Policy Analyst, CTP/Office of Compliance and Enforcement, Evonne.Bennett-Barnes@fda.hhs.gov

Our mission at CTP is to make tobacco-related death and disease part of America's past, not America's future. By working together, we can ensure healthier lives for your community.

Sincerely,

Mitchell Zeller
Director, Center for Tobacco Products

Enclosure

Exercise sovereignty. Control tobacco. Protect youth.

The Food and Drug Administration's Center for Tobacco Products

The Food and Drug Administration (FDA or the Agency) is an agency within the U.S. Department of Health and Human Services, with primary responsibility for protecting the public's health by regulating human and veterinary drugs, medical devices, foods, dietary supplements, and cosmetics, among other things. FDA's Center for Tobacco Products seeks to partner with federally recognized Tribes to educate retailers operating in Indian Country about the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act or the Act), which amends the Food, Drug and Cosmetic Act. FDA wishes to cooperatively enforce retailer requirements under the Tobacco Control Act, to ensure all youth are protected from marketing and tobacco sales violations that place them at risk.

Family Smoking Prevention and Tobacco Control Act

In 2009, President Obama signed the Tobacco Control Act into law. The Act is designed to protect public health and reduce tobacco use by children and adolescents by granting FDA the authority to regulate the manufacture, distribution, and marketing of tobacco products. Under the Tobacco Control Act, FDA hopes to work with Tribes to make tobacco-related death and disease part of the past in Tribal communities.

88% of adult daily smokers had their first cigarette before age 18.

The Tobacco Control Act and rules authorized under the Act:

- Establishes within FDA the Center for Tobacco Products to implement the Tobacco Control Act.
- Recognizes that virtually all new users of tobacco products are youth, under the age 18, prohibits the sale of cigarettes or smokeless tobacco to anyone under the age of 18, and restricts product advertising and marketing strategies that are designed to appeal to youth;
- Gives FDA immediate jurisdiction over cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and allows FDA to regulate additional tobacco products through rulemaking;
- Prohibits false or misleading advertising and labeling of regulated tobacco products;
- Gives FDA enforcement authority to pursue sanctions for violations of the Tobacco Control Act (e.g. Warning Letters, Civil Money Penalties, No-Tobacco-Sale orders); and
- Allows FDA to contract with states, territories, and Tribes to assist FDA with its enforcement responsibilities through retail inspections.

The Act Recognizes Tribal Sovereignty

FDA respects Tribal sovereignty and honors the government-to-government relationship it has with federally recognized American Indian and Alaska Native (AI/AN) Tribes. The Tobacco Control Act specifically:

- Does not limit authority of Tribes to enact, adopt, promulgate and enforce additional laws or regulations in addition to, or more stringent than, the Tobacco Control Act.
- Directs FDA to contract with states to carry out inspections of retailers within that State, and prohibits FDA from contracting with any State to exercise enforcement authority under the Act in Indian Country without the express written consent from the Tribe involved.

Exercise sovereignty. Control tobacco. Protect youth.

Protecting Tribal Youth

According to the Centers for Disease Control and Prevention (CDC), AI/AN youth have the highest prevalence of smoking (31.5%) compared to any other population group in the United States. In 2011, 24.7% of

AI/AN youth smoked a cigarette before age 13 as compared to a rate of only 10.3% for the total youth population within the United States.¹ The same CDC-sponsored study found that cigarette use among AI/AN high school students was 31.2%, compared to the total U.S. high school population at 18.1%.² As a whole, AI/ANs have an especially high risk of suffering from tobacco-related death and disease. Tobacco control policies are cost-effective ways to decrease tobacco abuse, which reduces tobacco-related diseases and deaths and improves community health.

According to the CDC, American Indian and Alaska Native youth have the highest prevalence of smoking compared to any other population group in the United States.

Tribal Governments – Part of the Solution

Tribal governments, working in partnership with FDA's Center for Tobacco Products, can help ensure all retailers and manufacturers on Indian country comply with the requirements of the Tobacco Control Act, which focus on protecting public health. Tobacco retailers and manufacturers are required to follow the Act, with regard to the manufacture, distribution, and marketing of regulated tobacco products.

FDA is inviting Tribes to engage in a collaborative and respectful government-to-government approach to the enforcement of the Tobacco Control Act. FDA intends to provide contract funds to Tribal governments to help implement and enforce the retail provisions of the Act. Tribes would need to submit a proposal to FDA to participate in forthcoming contracting opportunities.

The Tobacco Control Act includes some of the following restrictions:

- Prohibits the sale of cigarettes or smokeless tobacco to people younger than 18,
- Prohibits the sale of cigarette packages with less than 20 cigarettes,
- Prohibits distribution of free samples of cigarettes,
- Restricts distribution of free samples of smokeless tobacco, and
- Prohibits tobacco brand name sponsorship of any athletic, musical or other social or cultural

FDA is authorized to enforce the requirements of the Tobacco Control Act across the United States, including in Indian Country. FDA seeks to do this cooperatively with Tribal governments. Through a partnership, we can protect the health of our Native communities, including youth, by ensuring compliance with the Family Smoking Prevention and Tobacco Control Act.

For more information: <http://www.fda.gov/TobaccoProducts/default.htm>

Working together, we can ensure healthier lives for your community.

¹ CDC. Youth Risk Behavior Surveillance System (YRBSS). Youth Online Home. High School Youth Risk Behavior Survey: Smoked a Whole Cigarette For the First Time before Age 13 Years. <http://goo.gl/xePgyp>

² CDC. YRBSS. Youth Online Home. High School Youth Risk Behavior Survey: Current Cigarette Use. 2011 results. <http://goo.gl/Je1LTW>