DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration Center for Tobacco Products 10903 New Hampshire Silver Spring, MD 20993

March 13, 2015

Dear Tribal Leader:

The Center for Tobacco Products (CTP) within the U.S. Food and Drug Administration (FDA) understands the importance of collaboration and consultation, as appropriate, with tribal governments on the implementation and enforcement of the Family Smoking and Tobacco Control Act, a public health law designed to reduce the death and disease caused by tobacco.

Retailers play a critical 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. According to the Centers for Disease Control and Prevention, American Indian and Alaska Native youth are at a greater risk of becoming addicted to cigarettes than any other minority in the United States.¹

FDA contracts with states, territories and Tribes, in a collaborative approach to enforcement to help protect youth. Through this collaboration, we can help ensure youth are protected from violative marketing and sales of FDA-regulated tobacco products that place them at risk. FDA is announcing a Request for Proposals (RFP) that will issue on or about March 13, 2015, to contract with Tribes to conduct compliance check inspections of tobacco product retailers to determine retailer compliance with FDA's regulations on Tribal lands.

RFP and Technical Assistance Webinar:

FDA plans to host two webinars to discuss this tobacco retail inspection RFP, the process to submit proposals, and the work required under the resultant contracts.

Date Options:

Wednesday, April 1, 2015 Thursday, April 16, 2015

Time:

1:00 - 3:00 PM EST

Registration for either webinar:

http://tinyurl.com/rfpwebinar

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. 2013. http://nccd.cdc.gov/YouthOnline/App/Default.aspx

Link to RFP for Indian Tribes to conduct inspections on the retail requirements under the Family Smoking and Tobacco Control Act is available at: http://tinyurl.com/mmtuz6n.

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

Additionally, FDA posts retailer materials, including videos and other information at: www.fda.gov/TobaccoProducts/ResourcesforYou.

FDA respects Tribal sovereignty and honors the government-to-government relationship it has with Tribes. 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

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,

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

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.

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.

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

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.

Al/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. The same CDC-sponsored study found that cigarette use among Al/AN high school students was 31.2%, compared to the total U.S. high school population at 18.1%. As a whole, Al/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.

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