



December 22, 2016

Dear Tribal Leader:

The Food and Drug Administration (FDA) is pleased to provide you with the FDA Tribal Consultation Policy. The FDA Tribal Consultation Policy is intended to further the government-to-government relationship between FDA and American Indian and Alaska Native Tribes and to facilitate tribal consultation with FDA.

As you are aware, on February 29, 2016, we sent out a Draft FDA Tribal Consultation Policy and issued a notice in the Federal Register requesting comments, feedback and recommendations (FDA-2016-N-0586). FDA also provided information about the draft policy at the 2016 Annual HHS Tribal Budget and Policy Consultation and consulted with Indian Tribes during an All Tribes' Call in April 2016. The Agency reviewed and considered all comments on the draft policy and addressed this feedback in the FDA Tribal Consultation Policy, which is enclosed and also available on the FDA Tribal Affairs website www.fda.gov/tribal.

If you have any questions regarding the FDA Tribal Consultation Policy or FDA's consultation activities with federally recognized tribal governments, please contact Sarah Walinsky on the Intergovernmental Affairs Staff, at Sarah.Walinsky@fda.hhs.gov or (240) 402-4075. The FDA Intergovernmental Affairs Staff is available to assist Indian Tribes.

I want to thank you for your contributions to this process. I look forward to continuing to strengthen the relationship between FDA and tribal governments and to working with you to protect and advance the health of American Indian and Alaska Native communities.

Sincerely,



Leslie Kux
Associate Commissioner for Policy

Enclosure