



February 29, 2016

Dear Tribal Leader:

The U.S. Food and Drug Administration (FDA) is pleased to announce the availability of our draft FDA Tribal Consultation Policy. We are seeking your comments, feedback, and recommendations on this draft policy which will guide the development of a final FDA Tribal Consultation Policy. We are committed to honoring the special relationship between American Indian and Alaskan Native tribal governments and the United States government.

The draft FDA Tribal Consultation Policy is intended to, when finalized, establish clear policies to further the government-to-government relationship between FDA and Indian Tribes and to facilitate consultation with FDA. The draft policy is based on the Department of Health and Human Services (HHS) Tribal Consultation Policy. We have enclosed a copy of the draft FDA Tribal Consultation Policy for your information and review. A copy is also available on FDA's Tribal Affairs website:

<http://www.fda.gov/ForFederalStateandLocalOfficials/TribalAffairs/default.htm>.

Submitting Comments

We invite your comments on the draft FDA Tribal Consultation Policy (Docket No. FDA-2016-N-0586) as well as your suggestions on how we can improve our communication and outreach with tribal governments. You may submit comments, by any of the following methods:

- Electronic comment submissions
 - Follow the instructions for submitting comments on the Federal eRulemaking Portal at <http://www.regulations.gov>.
- Written comment submissions
 - Mail/hand deliver/courier (for paper or CD-ROM submissions) to
Division of Dockets Management, HFA-305, Food and Drug Administration
5630 Fishers Lane, Room 1061, Rockville, MD 20852

All submissions received must include the relevant docket number, Docket No. FDA-2016-N-0586. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. Please submit comments by May 31, 2016.

All Tribes Call

In addition to soliciting your written comments on the draft FDA Tribal Consultation Policy, we will be hosting an All Tribes' Call to provide an overview of the consultation policy, hear comments and answer questions about the draft policy.

All Tribes Call Information:

Thursday, April 21, 2016 from 2:30 PM- 4:00 PM EST
Toll-free number (for domestic callers): 1-888-950-9409
Toll number (for international callers): 1-312-470-7369
Passcode: FDA

Instant replay info:

Toll-free number: 866-433-1159

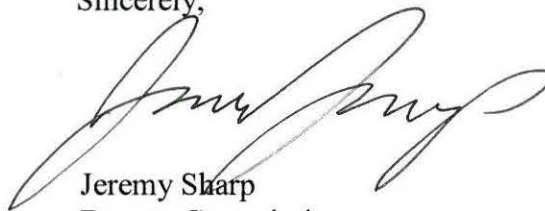
Toll number: 203-369-0996

The instant replay service will be available beginning approximately 1 hour after the call ends and will be available for 30 days.

If you have any questions regarding the Tribal Consultation Policy or other questions about FDA's consultation activities with federally recognized tribal governments, please contact Brian Kehoe, Acting Director of Intergovernmental Affairs, at Brian.Kehoe@fda.hhs.gov or (301) 796-8913.

We look forward to continuing to strengthen the relationship between FDA and tribal governments and continue our efforts to protect and advance the health of American Indian and Alaskan Native communities.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jeremy Sharp', written in a cursive style.

Jeremy Sharp
Deputy Commissioner
Office of Policy, Planning, Legislation & Analysis