



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0586]

Draft Food and Drug Administration Tribal Consultation Policy; Availability; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of the draft FDA Tribal Consultation Policy. We are also announcing the establishment of a docket to receive comments on the draft FDA Tribal Consultation Policy. The purpose of the FDA Tribal Consultation Policy, when finalized, is to establish clear policies to further the government-to-government relationship between FDA and American Indian and Alaskan Native Tribes (hereafter, Indian Tribes) and facilitate tribal consultation with FDA. The draft FDA Tribal Consultation Policy provides background on FDA's mission and organizational structure and sets out principles and guidelines for the tribal consultation process.

DATES: Comments must be received on or before May 31, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your

comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-N-0586 for "Draft FDA Tribal Consultation Policy; Availability; Request for Comments." Received comments will be placed in the docket and, except for those submitted as "Confidential

Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian Kehoe, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-8913.

SUPPLEMENTARY INFORMATION:

### I. Background

Under Executive Order 13175 of November 6, 2000, executive departments and Agencies are charged with engaging in regular and meaningful consultation and collaboration with tribal officials in the development of Federal policies that have tribal implications and are responsible for strengthening the government-to-government relationship between the United States and Indian tribes. The Department of Health and Human Services (HHS) Tribal Consultation Policy, revised on December 14, 2010, further clarifies that each HHS Operating and Staff Division must have an accountable consultation process to ensure meaningful and timely input by Tribal officials in the development of policies that have Tribal implications. To date, FDA has followed the HHS Tribal Consultation Policy (available at <http://www.hhs.gov/about/agencies/iea/tribal-affairs/consultation/index.html>). The draft FDA Tribal Consultation Policy is based on the HHS Tribal Consultation Policy and includes Agency-specific consultation guidelines that complement the Department-wide efforts.

The purpose of the draft FDA Tribal Consultation Policy, when finalized, is to establish clear policies to further the government-to-government relationship between FDA and Indian Tribes and facilitate tribal consultation with FDA. The draft policy provides background on FDA's mission and organizational structure and sets out principles and guidelines for the tribal consultation process. FDA intends for its Tribal Consultation Policy to serve as a platform for

the Agency to create consistent and meaningful tribal consultation across FDA Centers and Offices.

FDA is announcing the establishment of a docket to receive comments on the draft FDA Tribal Consultation Policy. We invite tribal officials, tribal organizations, individual tribal members and other interested persons to comment on the draft FDA Tribal Consultation Policy. We are interested in any general comments or concerns that would help us improve our policy as well as suggestions on how can we improve our communication and outreach with Indian Tribes. FDA also intends to consult with Indian Tribal officials on the draft FDA Tribal Consultation Policy and summaries of these consultations will be placed in the docket.

## II. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/ForFederalStateandLocalOfficials/TribalAffairs/default.htm> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the document.

Dated: February 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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