



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Food and Drug Administration Tribal Consultation Policy; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of the FDA Tribal Consultation Policy. The purpose of the FDA Tribal Consultation Policy is to further the government-to-government relationship between FDA and American Indian and Alaskan Native Tribes (Indian Tribes) and facilitate tribal consultation with FDA. The FDA Tribal Consultation Policy provides background on FDA's mission and organizational structure and elaborates on the principles and guidelines in the U.S. Department of Health and Human Services (HHS) Tribal Consultation Policy. This policy finalizes the draft FDA Tribal Consultation Policy issued in February 2016.

ADDRESSES: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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: Sarah Walinsky, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, (240) 402-4075.

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 Indian tribal governments 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 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. The FDA Tribal Consultation Policy, which finalizes the draft FDA Tribal Consultation Policy issued in February 2016, is based on the HHS Tribal Consultation Policy and includes Agency-specific consultation guidelines that complement the Department-wide efforts.

The purpose of the FDA Tribal Consultation Policy is to further the government-to-government relationship between FDA and Indian Tribes and facilitate tribal consultation with FDA. The policy provides background on FDA's mission and organizational structure and elaborates on the principles and guidelines in the HHS Tribal Consultation Policy. We consulted with Indian Tribes on the FDA Tribal Consultation Policy, which is intended to serve as a platform for the Agency to create consistent and meaningful tribal consultation across FDA Centers and Offices. A copy of the final policy has also been shared with Indian Tribes in a letter to tribal leaders.

II. Electronic Access

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

Dated: December 29, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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