National Indian Health Board

Submitted via: http://*www.regulations.gov*

May 31, 2016

Deputy Commissioner Jeremy Sharp
Division of Dockets Management
HFA-305
Food and Drug Administration
Room 1061
5630 Fishers Lane,
Rockville, MD 20852

RE: FDA Tribal Consultation Policy, Request for Comments

Dear Deputy Commissioner Sharp:

On behalf of the National Indian Health Board (NIHB) and in response to the Food and Drug Administration's (FDA) Dear Tribal Leader Letter dated February 29, 2016, we are writing to provide you with NIHB's comments and recommendations on the FDA Tribal Consultation Policy.

Established in 1972, the NIHB is an inter-Tribal organization that advocates on behalf of Tribal governments for the provision of quality health care to all American Indians and Alaska Natives (AI/ANs). The NIHB is governed by a Board of Directors consisting of a representative from each of the twelve Indian Health Service (IHS) Areas. Each Area Health Board elects a representative to sit on the NIHB Board of Directors. In areas where there is no Area Health Board, Tribal governments choose a representative who communicates policy information and concerns of the Tribes in that area with the NIHB. Whether Tribes operate their entire health care program through contracts or compacts with IHS under Public Law 93-638, the Indian Self-Determination and Education Assistance Act (ISDEAA), or continue to also rely on IHS for delivery of some, or even most, of their health care, the NIHB is their advocate

The FDA, like each federal agency, has the legal obligation to execute the trust responsibilities of the federal government to American Indian and Alaska Native (AI/AN) Tribes, and abide by the provisions of Executive Order 13175. Recent legislation that has had notable influences on Tribal affairs include the Food Safety Modernization Act (FSMA), the Tobacco Control Act (TCA) and other regulations set forth by the Center for Tobacco Products. Although significant controversies arose around the perceived lack of consultation before the passage of the FSMA, we are pleased that the FDA has taken the initiative to update its protocols and remain hopeful that stronger, more transparent and precise consultation policies will ensure meaningful engagement.

After reviewing the revised FDA consultation policy, the NIHB has put forth questions for clarification and recommendations that improve the nature of the government-to-government relationship. Many of these recommendations are adapted models from other federal agencies that have set important precedents. Overall, we believe that the FDA's revisions are in agreement with Executive Order 13175; however, certain ambiguities require explication.

The FDA's Tribal consultation process revolves around the identification and communication of "critical events" that have Tribal implications, followed by open interactions between affected Tribes and the FDA, and eventually a joint resolution. Although it is certainly a positive that FDA wishes to communicate such events, it is essential that the FDA clearly define the parameters of what classifies as a "critical event" and that this is done in conjunction with Tribes. Many times, what FDA may deem insignificant may be construed as imperative to Tribes—and this possibility must be taken into consideration. Thus, we believe the following questions should be sufficiently defined in advance:

- **How will the FDA go about delineating the criterion for a critical event?**
- **Does the FDA Office of Intergovernmental Affairs—which is the FDA liaison for states and Tribes— provide input during deliberations of proposed rules with repercussions in Tribal communities?**
- **Provide clarification and process for when a Tribe can initiate Tribal consultation.**
- **How much correspondence is sufficient? Will it be uniform across all critical events or is it graduated to reflect the severity and significance of a regulation's implications for Tribes?**
- **If a new law affects multiple Tribes, how will the FDA ensure that a representative number of Tribes are thoughtfully and appropriately involved in the consultation process?**

The Department of Agriculture (USDA), Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH) all have internal staff and offices that are responsible for the direct and independent communication and assistance with Tribes. Namely, the USDA Office of Tribal Relations, CDC/ATSDR Tribal Advisory Committee, and NIH Tribal Consultation Advisory Committee are all self-regulating bodies that carry out the trust responsibilities of their corresponding agency through intra-office meetings and educational sessions, active consultation with Tribal representatives, and enforcement of Tribal inclusivity in all new protocols and procedures with potential Tribal implications. The FDA currently houses Tribal, state and territorial relations within their Office of Intergovernmental Affairs. This process is not always inclusive of Tribes, especially given the often turbulent relationship between Tribes and states. Tribes are sovereign governments with a unique and specific relationship with the federal government by virtue of treaty obligations, executive orders and other government-to-government resolutions. Furthermore, **we recommend that the FDA have a separate office specifically demarcated for consultation with Tribal governments, Inter-Tribal Organizations, or other representative bodies authorized to speak on behalf of their Tribal constituents in addition to informing fellow FDA offices of Tribal affairs**. This office can be staffed by Tribal leaders who are elected to advisory board positions, senior FDA staff with explicit experience working with Tribes, or national at-large members such as those from Native-led non-governmental organizations such as the NIHB or National Congress of American Indians.

Given the miscommunications that ensued following the passage of the FSMA, the FDA needs to take pro-active measures to ensure that timely, appropriate and comprehensive consultation occurs prior to enacting new legislation. Moreover, it is not appropriate for any federal agency to claim that sufficient consultation has occurred after merely one webinar, or that an agency's consultation duties are fulfilled if they reached out to Tribes and did not receive an immediate response. Agencies must take the barriers within Indian Country into consideration, including limited access to electronic forms of communication due to lack of IT infrastructure, lack of awareness or education around how the consultation process works, or inability to prepare commentary by a fixed deadline. These barriers must be acknowledged and accommodated for, so that consultations are as meaningful as possible. For this reason, the NIHB has included a summarized list of recommendations below:

- **Establish an internal body of staff that work specifically on FDA regulations and policies that have Tribal implications.**
- **Engage and work collaboratively with other federal agencies, so as to minimize redundancy and optimize efficiency to further ensure positive outcomes for Tribal communities.**
- **Allow Tribes to solicit consultation in addition to being approached for such by the FDA.**
- **Establish specific protocols for "…** ***consensual mechanisms for developing regulations, including negotiated rulemaking*****." Presently, FDA has no formal procedures for engaging Tribes in the mutual composition of regulations with Tribal implications.**
- **Clarify the parameters for "critical" versus "non-critical" events, and establish formal measures for how such events are determined and defined in advance.**
- **Given that no two critical or non-critical events are created equally, work with Tribes on a case-by-case basis to ensure that sufficient consultation has occurred.**
- **Work with Tribes individually and make accommodations for Tribes that are unable to correspond via traditional methods such as email or webinar. Although the FDA has created a list of consultation mechanisms, they have not** ***quantified*** **how much consultation is pertinent to a critical event, nor have they explicitly mentioned how they will engage Tribes that are unable to consult via traditional methods.**

We hope that the FDA, in the spirit of its partnership and shared interest in improving American Indian and Alaska Native (AI/AN) access to its resources and services, will work with the NIHB to improve the FDA Tribal Consultation Policy. We thank you for this opportunity to provide our comments and recommendations on FDA Tribal Consultation Policy. Should you have any questions or concerns, please direct them to NIHB's Director of Federal Relations, Devin Delrow, at ddelrow@nihb.org.

Sincerely,

Lester Secatero
Chairman, National Indian Health Board