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May 31, 2016

Deputy Commissioner Jeremy Sharp
Office of Policy, Planning, Legislation, & Analysis
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061,
Rockville, MD 20852

Re: Docket No. FDA-2016-N-0586 for “Draft FDA Tribal Consultation Policy; Availability; Request for Comments.”

Dear Deputy Commissioner Sharp,

The United South and Eastern Tribes Sovereignty Protection Fund (USET SPF) is pleased to provide the Food and Drug Administration (FDA) with the following comments in response to the Agency’s February 29, 2016 “Dear Tribal Leader” letter regarding its draft Tribal Consultation Policy. We are encouraged by FDA’s commitment to honor and further its role in the government-to-government relationship between Tribal Nations and the federal government. As agencies of the United States government, the Department of Health and Human Services (HHS) and its operating divisions, including the FDA, have sacred trust obligations to Tribal Nations. We offer the following comments in support of the establishment of FDA protocols for engaging with Tribal Nations and to ensure meaningful consultation in the development of policies impacting Indian Country.

USET SPF is a non-profit, inter-tribal organization representing 26 federally recognized Tribal Nations from Texas across to Florida and up to Maine¹. Both individually, as well as collectively through USET SPF, our member Tribal Nations work to improve health care services for American Indians. Our member Tribal Nations operate in the Nashville Area of the Indian Health Service (IHS), which contains 36 IHS and Tribal health care facilities. Our citizens receive health care services both directly at IHS facilities, as well as in Tribally-operated facilities operated under contracts with IHS pursuant to the Indian Self-Determination and Education Assistance Act (ISDEAA), P.L. 93-638.

Introduction

USET SPF welcomes the development of this consultation policy, as it seeks to meet the objectives set forth in Executive Order 13175 and reaffirmed by President Obama’s November 5, 2009 Executive Memorandum on Tribal Consultation. We appreciate the FDA’s commitment to meeting the first objective of the Department of Health and Human Services Tribal Consultation policy, “to formalize the Administration’s policy that HHS seek consultation and the participation of Indian Tribes in the development of policies and program activities that impact Indian Tribes.” Tribal Nations are regularly impacted by the FDA’s regulation of goods and services made available to Tribal citizens. In light

¹ USET SPF member Tribal Nations include: Alabama-Coushatta Tribe of Texas (TX), Aroostook Band of Micmac Indians (ME), Catawba Indian Nation (SC), Cayuga Nation (NY), Chitimacha Tribe of Louisiana (LA), Coushatta Tribe of Louisiana (LA), Eastern Band of Cherokee Indians (NC), Houlton Band of Maliseet Indians (ME), Jena Band of Choctaw Indians (LA), Mashantucket Pequot Indian Tribe (CT), Mashpee Wampanoag Tribe (MA), Miccosukee Tribe of Indians of Florida (FL), Mississippi Band of Choctaw Indians (MS), Mohegan Tribe of Indians of Connecticut (CT), Narragansett Indian Tribe (RI), Oneida Indian Nation (NY), Passamaquoddy Tribe at Indian Township (ME), Passamaquoddy Tribe at Pleasant Point (ME), Penobscot Indian Nation (ME), Poarch Band of Creek Indians (AL), Saint Regis Mohawk Tribe (NY), Seminole Tribe of Florida (FL), Seneca Nation of Indians (NY), Shinnecock Indian Nation (NY), Tunica-Biloxi Tribe of Louisiana (LA), and the Wampanoag Tribe of Gay Head (Aquinnah) (MA).

of this, a transparent and meaningful partnership between the FDA and Tribal Nations is imperative to the development of policies impacting Indian Country. It is in this spirit that USET SPF offers the following section-by-section recommendations for the improvement of FDA's consultation policy.

Section 2. Tribal Sovereignty

The recognition of inherent Tribal sovereignty and the right to Tribal self-government is critical to the facilitation of a true government-to-government relationship between Tribal Nations and the federal government. As written, this section does not currently reflect the full depth of our sacred relationship, nor does emphasize the vital importance of self-government.

RECOMMENDATION: USET SPF recommends that the language in this section be removed and replaced with the language within the HHS Tribal Consultation Policy Section 3, "Tribal Sovereignty," as the HHS policy more accurately describes a commitment to and recognition of Tribal sovereignty.

Section 3. Policy

Subsection C of this section doesn't accurately underscore the importance of FDA's responsibility to engage in meaningful consultation and utilize consensual mechanisms for developing and advancing rulemaking on matters related to Tribal self-government, Tribal trust resources, or Indian Tribal treaty and other rights.

RECOMMENDATION: USET SPF recommends that the language in this section be replaced with the language within the HHS Tribal Consultation Policy Section 4, Subsection D. This section provides stronger language recognizing the obligation of the federal government to engage in consensual, multilateral decision-making processes to produce sound policies for Indian country.

Section 5. Tribal Consultation Process

Subsection C, "Communication Methods"

We support the FDA's initiative to establish a specific 30 day deadline for the purposes of communicating with Tribal Nations in the determination of a "critical event." During cases in which an event will have "substantial impact on Indian Tribes" we support the 60 day window for convening associated meetings. Similarly, we appreciate FDA's commitment to reporting the outcomes of final consultation within 90 days of the encounter. We believe that codifying these protocols will support transparency and will result in a more productive working partnership between the Agency and Tribal Nations.

Subsection D, "FDA Reply to Official Tribal Correspondence"

As noted in the draft policy, official correspondence from a Tribal Nation may come in a multitude of different forms, including official letters or resolutions. USET SPF is concerned with current language in this section which states, "official correspondence from an Indian Tribe may come in various forms, but a resolution is the most formal declaration of an Indian Tribe's position for the purpose of Tribal Consultation." Tribal governments, like state governments or other governmental bodies, do not always pass formal resolutions for all policy positions or official statements.

RECOMMENDATION: USET SPF recommends the FDA recognize all official communications from Tribal Nations, provided they are certified by Tribal governmental letterhead, as official correspondence.

Tribal Nations, like the United States government, provide a variety of services and supports to their citizens, and delegate the authority to perform essential governmental functions to various operating divisions within their government administrations. The heads of these divisions, who are employed as staff of a Tribal Nation, may offer

official correspondence on behalf of the Nation for matters under that fall under their jurisdiction. For example, Tribal health directors often provide comments and testimony on matters related to the health of Tribal citizens or the operation of Tribal health facilities. This authority is undermined by language in this section which states, "correspondence from a Tribal staff person or Tribal member who is not elected or formally appointed to speak on behalf of the Indian Tribe or a Tribal leader will be responded to in accordance with FDA's established protocols and will not be considered official Tribal correspondence or a request for consultation." As is their right as sovereign nations, Tribal leadership may provide representatives from Tribal governmental operating divisions with the authority to issue official correspondence and/or submit a request for consultation on issues that impact the Nation.

RECOMMENDATION: USET SPF recommends the FDA remove the above language from Subsection D.

Section 6. Tribal Consultation Roles and Responsibilities

Subsection A, "Participant Roles and Responsibilities," is not inclusive of all entities with the authority to represent the interests of Tribal Nations during the consultation process. Tribal organizations, like USET, have governing bodies comprised of Tribal Leaders and are important vehicles for reaching consensus and advancing important policy positions. These organizations were formed with the express purpose of representing the interests and intentions of coalitions of Tribal Nations. As such, they are fully vested with the authority to speak on behalf of those nations, including during official interactions with the federal government. This section must reflect the variety of Tribal organizations which are authorized to engage in Tribal Consultation with FDA.

RECOMMEDATION: USET SPF recommends that FDA insert "Tribal Organizations" into the list of participants under Subsection A, to acknowledge the authority vested in these organizations to advocate on behalf of Tribal Nation interests.

Conclusion

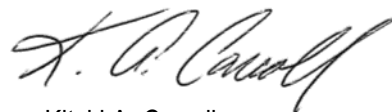
Like many HHS operating divisions before them, USET SPF is pleased with FDA's initiative to work with Tribal Nations to establish a Tribal Consultation Policy. This policy will be vital to FDA's efforts to deliver on its trust obligations to Tribal Nations. USET SPF looks forward to ongoing partnership, consultation, and dialogue with FDA on important issues affecting Indian Country.

Should you have any questions or require additional information, please do not hesitate to contact Ms. Liz Malerba, USET Director of Policy and Legislative Affairs, at (202) 624-3550 or by e-mail at lmalerba@usetinc.org.

Sincerely,



Brian Patterson
President



Kitcki A. Carroll
Executive Director

CC: USET member Tribes
Wanda James, USET Deputy Director
Dee Sabattus, USET Director of Tribal Health Program Support
Hilary Andrews, USET Health Policy Analyst

"Because there is strength in Unity"