

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
TRIBAL CONSULTATION POLICY (DRAFT)**

Table of Contents

1. Background and Purpose
2. Tribal Sovereignty
3. Policy
4. Background on U.S. Food and Drug Administration
5. Tribal Consultation Process
6. Tribal Consultation Roles and Responsibilities
7. Health and Human Services Budget Formulation
8. Tribal Consultation Evaluation, Performance, and Accountability
9. Conflict Resolution
10. Tribal Waiver
11. Effective Date
12. Definitions
13. Acronyms

1. Background and Purpose

The Food and Drug Administration (FDA), an operating division within the U.S. Department of Health and Human Services (HHS), adheres to the HHS Tribal Consultation Policy, which serves as a guide for federally recognized Indian or Alaska Native Tribes (hereafter, Indian Tribes) to participate in policy development by HHS and its divisions to the greatest extent practicable and permitted by law. The purpose of the FDA Tribal Consultation Policy is to establish clear policies to further the government-to-government relationship between FDA and Indian Tribes and facilitate tribal interaction with FDA. Nothing in the FDA Tribal Consultation Policy shall be construed as diminishing or waiving the HHS Tribal Consultation Policy.

Consultation is an enhanced form of communication which emphasizes trust, respect, and shared responsibility. The special government-to-government relationship between the federal government and Indian Tribes is based on the Constitution and has been given form and substance by numerous treaties, laws, Executive Orders, and federal court decisions. The importance of consultation with Indian Tribes was affirmed through Presidential Memoranda in 1994, 2004, and 2009, and Executive Order (EO) 13175 in 2000. FDA is committed to furthering relationships with Indian Tribes by engaging in open, continuous, and meaningful consultation to promote exchange of information, mutual understanding, and informed decision-making.

2. Tribal Sovereignty

Since the formation of the Union, the United States has recognized Indian Tribes as sovereign nations under its protection and recognized the right of Indian Tribes to self-government. Self-government means government in which the people who are most directly affected by the decisions make the decisions. Indian Tribes exercise certain inherent sovereign powers over their members and territory.

Consistent with Section 3 of the HHS Tribal Consultation Policy (Tribal Sovereignty), this policy does not waive any tribal governmental rights or authority, including treaty rights, sovereign immunities, or jurisdiction. Additionally, this policy does not diminish any rights or protections afforded other American Indians or Alaskan Natives or related entities under Federal law.

3. Policy

To the extent practicable and permitted by law, consultation with Indian Tribes will occur before any policy action is taken that has tribal implications and substantial direct effects on:

- one or more Indian Tribe(s), or
- on the relationship between the Federal Government and the Indian Tribe(s), or
- on the distribution of power and responsibilities between the Federal Government and the Indian Tribe(s).

A policy action includes actions such as the promulgation of a regulation and excludes actions related to compliance, enforcement, product applications, or other submissions which are not made public during FDA's review or are otherwise protected from public disclosure.

Nothing in this policy waives the Government's deliberative process privilege. Examples of the government's deliberative process privilege include:

1. Reports, recommendations or other products governed by OMB Circular No. A-19: Legislative Coordination and Clearance.
2. Members of Congress specifically request the Department or FDA to respond to or report on proposed legislation, the development of such responses and of related policy is a part of the Executive Branch's deliberative process privilege and should remain confidential.
3. FDA regulations prohibit the Agency from providing a draft of a notice or proposed regulation or its preamble, or a portion of either, to an interested person outside the executive branch unless it is made available to all interested persons by a notice published in the Federal Register (21 CFR 10.80). Once it is determined that a notice or proposed regulation will be prepared, a representative of FDA may only discuss the general concepts.

The implementation of the FDA Tribal Consultation Policy will adhere to the following guidelines:

- A. The FDA will follow the Tribal Consultation Process guidelines set forth in Section 5 of the FDA Tribal Consultation Policy to ensure meaningful and timely input by Indian Tribes in the development of policies that have tribal implications.
- B. To the extent practicable and permitted by law, the FDA shall not promulgate any regulation that has tribal implications and that preempts tribal law or imposes substantial direct-compliance costs on Indian Tribal governments, and that is not required by statute, unless:
 1. funds necessary to pay the direct costs incurred by the Indian Tribal government or the Indian Tribe(s) in complying with the regulation are provided by the Federal Government; or
 2. the FDA, prior to the formal promulgation of the regulation:
 - a. consulted with Indian Tribes throughout the process of developing the regulation;

- b. provided, in a separately identified portion of the preamble to the regulation as it is to be issued in the Federal Register (FR), a Tribal summary impact statement, which consists of a description of the extent of FDA's prior consultation with Tribal Officials, a summary of the nature of their concerns and the Agency's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of Tribal Officials have been met; and
 - c. made available to the Secretary of HHS any written communications regarding the proposed regulation submitted to FDA by Tribal Officials.
- C. On issues relating directly to tribal self-government, tribal trust resources, or Indian Tribal treaty and other rights, FDA shall explore and, where appropriate, use consensual mechanisms for developing regulations, including negotiated rulemaking.

4. Background on the U.S. Food and Drug Administration

FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, the nation's food supply, cosmetics, and products that emit radiation. FDA also advances the public health by helping to speed innovations that make medicines more effective, safer, and more affordable, and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health. Furthermore, FDA has responsibility for regulating the manufacture, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. Finally, FDA plays a significant role in the nation's counterterrorism capability by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.

- A. Major authorizing statutes for FDA include:
 - The Federal Food, Drug & Cosmetic Act (P.L. 75-717), as amended (21 U.S.C. 301 *et seq.*);
 - The Public Health Service Act (P.L. 78-140), as amended (42 U.S.C. 201 *et seq.*)
- B. Key FDA Offices and Centers include (more information is available at FDA.gov):

The Office of the Commissioner: FDA is headed by the Commissioner of Food and Drugs. The Office of the Commissioner includes the Office of Policy Planning, Legislation, and Analysis (which includes the Intergovernmental Affairs staff), the Office of Foods and Veterinary Medicine, the Office of Medical Products and Tobacco, the Office of Global Regulatory Operations and Policy, the Office of Minority Health, the Office of Women's Health, and the Office of Special Medical Products.

The Center for Biologics Evaluation and Research (CBER) regulates a wide range of biological products, such as vaccines, blood and blood components, allergenics, cells and tissues, gene therapy, and certain recombinant therapeutic proteins. Biological products are either isolated from a variety of natural sources - human, animal, or microorganism – or are produced by one of several different cutting edge technologies.

The Center for Drug Evaluation and Research (CDER) regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. CDER's principal

functions are to review the evidence that prescription and over-the-counter human drugs (both brand name and generic) are safe and effective before allowing them to be marketed; monitor their use for unexpected health risks; ensure their continued high quality; and oversee the accuracy and completeness of drug information provided for health professionals and consumers.

The Center for Devices and Radiological Health (CDRH) is responsible for assuring the safety, effectiveness, and quality of medical devices, and ensuring the safety of radiation-emitting electronic products (medical and non-medical) such as lasers, x-ray systems, ultrasound equipment, and microwave ovens. CDRH is responsible for regulating firms that manufacture, repack, relabel, and/or import medical devices sold in the United States. FDA has classified medical devices into Class I, II, and III. Classification is based upon the controls deemed necessary to provide adequate assurance of safety and effectiveness. Regulatory control increases from Class I devices, which mostly are exempt from Premarket Notification, to Class III, which require Premarket Approval.

The Center for Food Safety and Applied Nutrition (CFSAN) regulates human food to help ensure that the nation's food supply (everything we eat except for meat, poultry, and some egg products that are regulated by the U.S. Department of Agriculture) is safe, sanitary, wholesome, and honestly labeled and that cosmetics are safe and properly labeled.

The Center for Tobacco Products (CTP) regulates the manufacture, distribution, and marketing of tobacco products to protect public health. Some of CTP's responsibilities include setting performance standards, reviewing premarket applications for new and modified risk tobacco products, requiring new warning labels, and establishing and enforcing advertising and promotion restrictions.

The Center for Veterinary Medicine (CVM) regulates and monitors animal food, animal drugs, and animal devices. The Center ensures a drug is safe and effective before approving the drug. These are drugs for companion animals such as dogs, cats, and horses, and food-producing animals such as cattle, chickens, and swine, and include prescription and over-the-counter drugs. In addition, if the drug is for a food-producing animal, the Center ensures food products derived from animals treated with the drug are safe for human consumption. The Center also regulates animal food—which includes animal feed, pet food, and pet treats—to help ensure it is safe, made under sanitary conditions, and properly labeled.

The National Center for Toxicological Research (NCTR) is a research institute that conducts scientific research to develop a scientifically sound basis for regulatory decisions and reduce risks associated with FDA-regulated products.

The Office of Regulatory Affairs (ORA) provides leadership for all FDA field activities and policies involving imports, inspections, and enforcement. ORA supports the FDA product centers by inspecting regulated products and manufacturers, conducting sample analysis on regulated products, and reviewing imported products offered for entry into the United States. ORA also develops FDA-wide policy on compliance and enforcement and executes FDA's import strategy and food protection plans.

The Office of International Programs (OIP) works with governments, industry and academia in foreign countries, as well as with multilateral organizations, to help assure that food and medical products exported to the United States meet U.S. standards.

5. Tribal Consultation Process

- A. **Identification of a Critical Event:** A critical event, which is defined as a planned or unplanned policy action that has or may have tribal implications and substantial direct effects on Indian Tribe(s), may be identified by FDA and/or an Indian Tribe(s).

The following serve as guidelines to be utilized when FDA and/or an Indian Tribe (s) identify a critical event:

1. Identify the critical event, as well as the complexity, implications, time constraints, and issue(s) involved (e.g., policy, funding/budget development, programs, services, functions, or activities).
 2. Identify the affected/potentially-affected Indian Tribe(s).
 3. Identify the most useful and appropriate consultation mechanism(s).
- B. **Consultation Mechanisms:** Consultation mechanisms include but are not limited to one or more of the following:
- a. Written Communication
 - b. Teleconferences
 - c. Meetings (face-to-face, via webinar, or video conference) at the local, regional, or national levels between FDA and Indian Tribes
 - d. Roundtables
 - e. Annual HHS Tribal Budget and Policy consultation sessions
 - f. Consultation sessions held at tribal organization meetings where many Indian Tribes or tribal officials are likely to be represented
 - g. Other regular or special HHS Division or program level consultation sessions.
- C. **Communication Methods:** FDA shall communicate the determination of the critical event and the consultation mechanism to be used to affected/potentially-affected Indian Tribe(s) using appropriate methods and with as much advance notice as practicable. These methods include but are not limited to the following:
1. *Correspondence:* FDA shall issue written communications within 30 calendar days of an identified critical event. The communication should clearly provide affected/potentially-affected Indian Tribe(s) with details of the critical event and the manner and timeframe in which to provide comment. FDA may use a “Dear Tribal Leader” (DTL) letter format to notify individual Indian Tribes of consultation activities. Centers and Offices will work with the HHS Office of Intergovernmental Affairs and the FDA Intergovernmental Affairs staff if technical assistance is required for proper format, protocols, current mailing lists, and content.
 2. *Official Notification:* Upon the determination of a consultation mechanism other than written communication, FDA shall give proper notice of the critical event and the

consultation mechanism to be utilized to affected/potentially-affected Indian Tribe(s) within 30 calendar days, using appropriate methods, such as a DTL mailing, broadcast e-mail, Federal Register Notice, or other outlets. The Federal Register is the most formal form of notice used for consultation.

3. *Meeting(s)*: When FDA has determined the critical event to have substantial impact on Indian Tribes, FDA shall convene a meeting, within 60 calendar days of official notification, with the affected/potentially-affected Indian Tribe(s) to discuss all pertinent issues in a national, regional, and/or local forum, as appropriate, to the extent practicable and permitted by law.
 5. *Receipt of Tribal Comment(s)*: FDA shall use appropriate methods to communicate clear and explicit instructions on the means and time frames for Indian Tribe(s) to submit comments on the critical event. Where public comment is sought on a proposed rule, FDA will provide the docket number and deadline for comments to be received. All comments that are submitted to the docket during the comment period, including those submitted by Indian Tribes, will become part of the official rulemaking record. FDA will also submit to the related docket all transcripts and summaries of consultation sessions conducted in conjunction with a proposed rule. FDA will review the entire rulemaking record, including all comments, transcripts, and summaries submitted to the docket, when finalizing the rulemaking.
 6. *Reporting of Outcome*: Consistent with Section 8 of the FDA Tribal Consultation Policy, FDA shall report on the outcomes of the consultation within 90 calendar days of the final consultation. For ongoing issues identified during the consultation, FDA shall provide status reports throughout the year to the HHS Office of Intergovernmental Affairs and the Indian Tribe(s).
- D. **FDA Reply to Official Tribal Correspondence**: 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. In some instances, Indian Tribes will submit official correspondence from the highest elected and/or appointed official(s) of the Indian Tribe. FDA will give equal consideration to these types of correspondence. 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.

When FDA receives an official Indian Tribe correspondence and/or resolution, the FDA Commissioner/Deputy Commissioner/Associate Commissioner/Center Director and/or their designee shall respond appropriately. The process for official FDA correspondence responding to an Indian Tribe is described below:

1. *Receipt of Correspondence*: Correspondence submitted by Indian Tribes to FDA that does not identify a specific public docket shall be entered into the FDA correspondence control tracking system and referred to the appropriate Office or Center.

2. *Acknowledgement of Correspondence:* FDA shall provide acknowledgement to Indian Tribes of letters entered into the FDA correspondence control tracking system within 15 working days of receipt.
 3. *Official Response to an Identified Critical Event:* FDA shall provide an official response to Indian Tribes that includes: the FDA Office or Center responsible for follow up, the process for resolution of the critical event, and a timeline for resolution.
 - a. If an identified critical event is national in scope, the FDA shall, to the extent practicable, respond to the request within 60 working days or less.
 - b. If a critical event is specific to a single Indian Tribe, the FDA shall, to the extent practicable, respond to the request within 45 working days or less.
- E. **Policy Development through Tribal Consultation Process:** The need to consult on the development or revision of a policy may be identified from within FDA or may be identified by Indian Tribes. This need may result from external forces such as executive, judicial, or legislative branch actions or otherwise. Once the need to consult on a policy action is identified, the consultation process will begin in accordance with the identification of the critical event and consultation mechanisms described above, as appropriate.
- F. **Schedule for Consultation:** As needed, FDA may establish a formal schedule of meetings to consult with Indian Tribes and their representatives concerning the planning, conduct, and administration of applicable activities.

6. Tribal Consultation Roles and Responsibilities

A. Participant Roles and Responsibilities:

1. *Consultation Parties:* Consultation occurs when the FDA Consultation Party (FDA Commissioner/Deputy Commissioner/Associate Commissioner/Center Director), or a designee, meets in person or via teleconference or webinar or exchanges written correspondence with a Tribal Consultation Party (Tribal President/Chair/Governor/Chief/Principal Chief and/or elected/appointed Indian Tribal Leader), or a designee, to discuss issues or concerns of either Party. Each party will identify its authorized representative(s) with delegated authority to act on its behalf.
2. *Indian Tribes:* The government-to-government relationship between the United States and federally recognized Indian Tribes dictates that the principal focus for FDA consultation is Indian Tribes, individually or collectively.
3. *Indian Organizations:* At times it is useful for the FDA to communicate with Indian organizations to solicit Indian Tribe(s) advice and recommendations. The federal government does not participate in government-to-government consultations with these entities; rather, these organizations represent the interest of Indian Tribes when authorized by those Tribes. These organizations by the sheer nature of their business serve and advocate for the issues and concerns of Indian Tribes that might be affected if these organizations were excluded from the process.

4. *FDA Intergovernmental Affairs*: The FDA Intergovernmental Affairs (IGA) staff, within the Office of the Commissioner's Office of Policy, Planning, Legislation, and Analysis, is the FDA liaison to States and Indian Tribes and the staff's mission is to facilitate communication regarding FDA policy initiatives as they relate to Tribal, State, and local governments. In addition, some FDA Centers have staff that may work directly with Indian Tribes in coordination with the FDA IGA staff.

7. Health and Human Services Budget Formulation

FDA will comply with Section 11 of the HHS Tribal Consultation Policy concerning Budget Formulation.

8. Tribal Consultation Evaluation, Performance, and Accountability

The consultation process and activities conducted according to this policy should result in meaningful outcomes for FDA and for the affected Indian Tribes. To effectively evaluate the results of consultation activity and FDA's ability to incorporate the input of Indian Tribes, FDA will comply with Section 12 of the HHS Tribal Consultation Policy concerning Tribal Consultation Performance and Accountability and Section 13 concerning Evaluation, Recording of Meetings, and Reporting. Included among these activities, FDA will maintain a record of all consultations and will contribute to the "HHS Annual Tribal Consultation Report," which describes consultation activity, including outcomes, as outlined in Section 13 of the HHS Tribal Consultation Policy.

9. Conflict Resolution

The intent of this policy is to promote partnerships with Indian Tribes that enhance FDA's ability to address tribal issues, needs, and problems. However, Indian Tribes and FDA may not always agree, and inherent in the government-to-government relationship, Indian Tribes may elevate an issue of importance to a higher or separate decision-making authority. FDA will comply with Section 14 of the HHS Tribal Consultation Policy concerning Conflict Resolution.

Nothing in the FDA Tribal Consultation Policy creates a right of action against FDA or HHS for failure to comply with this Policy.

10. Tribal Waiver

FDA will process all requests routinely received for waivers under existing program authorities within the statutorily set timeframes.

11. Effective Date

The FDA Tribal Consultation Policy is effective [on the date of signature by the FDA Commissioner].

12. Definitions

Following is a list of definitions for this policy document. (Further information about FDA and its Centers is included in Section 4 of this policy.):

Agency: The Food and Drug Administration

Communication: The exchange of ideas, messages, or information, by speech, signals, writing, or other means.

Consultation: An enhanced form of communication, which emphasizes trust, respect, and shared responsibility. It is an open and free exchange of information and opinion among parties, which leads to mutual understanding and comprehension. Consultation is integral to a deliberative process, which results in effective collaboration and informed decision-making with the ultimate goal of reaching consensus on issues.

Critical Event: A planned or unplanned policy action that has or may have tribal implications and substantial direct effects on Indian Tribe(s).

Deliberative Process Privilege: A privilege exempting the government from disclosure of government agency materials containing opinions, recommendations, and other communications that are part of the decision-making process within the Agency.

Executive Order: An order issued by the President on the basis of authority specifically granted to the Executive Branch (as by the U.S. Constitution or a Congressional Act).

Federally Recognized Indian Tribes: Indian Tribes with whom the Federal Government maintains an official government-to-government relationship; usually established by a Federal treaty, statute, executive order, court order, or a Federal Administrative Action. The Bureau of Indian Affairs (BIA) maintains and regularly publishes the list of federally-recognized Indian Tribes.

Indian Organization: 1) Those federally recognized tribally constituted entities that have been designated by their governing body to facilitate communications and consultation activities with HHS; or 2) Any regional or national organizations whose board is comprised of federally recognized Indian Tribes and elected/appointed Tribal leaders. The Federal Government does not participate in government-to-government consultation with these entities; rather these organizations represent the interests of Tribes when authorized by those Tribes.

Indian Tribe: An Indian or Alaska Native tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian Tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994, (25 U.S.C. 479a).

Policy Action: Includes FDA actions such as the promulgation of rules, and excludes actions related to compliance, enforcement, product applications, or other submissions which are not made public during FDA's review or are otherwise protected from public disclosure.

Policies with Tribal Implications: Policy actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

Self-Government: Government in which the people who are most directly affected by the decisions make the decisions.

Sovereignty: The ultimate source of political power from which all specific political powers are derived.

Substantial Direct Compliance Costs: Those costs incurred directly from implementation of changes necessary to meet the requirements of a Federal regulation. Because of the large variation in Tribes, “substantial costs” is also variable by Indian Tribe. Each Indian Tribe and the Secretary shall mutually determine the level of costs that represent “substantial costs” in the context of the Indian Tribe’s resource base.

To the Extent Practicable and Permitted by Law: Refers to situations where the opportunity for consultation is limited because of constraints of time, budget, legal authority, etc.

Treaty: A legally binding and written agreement that affirms the government-to-government relationship between two or more nations.

Tribal Government: An American Indian or Alaska Native Tribe, band, nation, pueblo, village or community that the Secretary of the Interior acknowledges to exist as an Indian Tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994, (25 U.S.C. 479a).

Tribal Officials: Elected or duly appointed officials of Indian Tribes or authorized inter-Tribal organizations.

Tribal Organization: The recognized governing body of any Indian Tribe; any legally established organization of Indians which is controlled, sanctioned, or chartered by such governing body or which is democratically elected by the adult members of the Indian community to be served by such organization and which includes the maximum participation of Indians in all phases of its activities: Provided, that in any case where a contract is let or grant made to an organization to perform services benefiting more than one Indian Tribe, the approval of each such Indian Tribe shall be a prerequisite to the letting or making of such contract or grant.

Tribal Resolution: A formal expression of the opinion or will of an official Tribal governing body which is adopted by vote of the Tribal governing body.

Tribal Self-Governance: The governmental actions of Indian Tribes exercising self-government and self-determination.

13. ACRONYMS

BIA:	Bureau of Indian Affairs
CFR:	Code of Federal Regulations
FDA:	Food and Drug Administration
FR:	Federal Register
HHS:	U.S. Department of Health and Human Services
OMB:	Office of Management and Budget
U.S.:	United States
U.S.C.:	United States Code