DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

March 27, 2014

Dear Tribal Leader:

On Wednesday, April 23, 2014, the U.S. Food and Drug Administration (FDA) will host a Tribal Consultation from 8:30 a.m. to 11:00 a.m. MDT, at the Indian Pueblo Cultural Center, Chaco 1, 2401 12th Street, NW, Albuquerque, New Mexico, to discuss FDA's proposed rules required by the FDA Food Safety Modernization Act (FSMA), including our intent to prepare an Environmental Impact Statement (EIS) for the proposed rule entitled "Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption" (the produce safety proposed rule). This consultation is being held in response to requests by tribal leaders.

FDA will provide background information primarily on the produce safety proposed rule based on the expression of interest we have received from tribal officials. FDA's intent to prepare an EIS to evaluate the potential significant environmental impacts of the produce safety proposed rule, which FDA announced on August 20, 2013, will also be discussed. In addition, FDA will provide information and answer any questions about six other proposed rules required by FSMA. Tribes are invited to share perspectives, feedback, and any specific questions or concerns about these proposed rules and, for purposes of the EIS, any potential significant environmental impacts on a reservation that may result from the produce safety proposed rule.

Information on all seven FSMA proposed rules is included in the enclosure to this letter and is also available at http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm.

To register to attend the Tribal Consultation, please contact Kelly Malone, Office of Foods and Veterinary Medicine, at 301-796-4731 or email kelly.malone@fda.hhs.gov.

I hope you are able to join us for this meeting, and I thank you for your interest in food safety. The FDA looks forward to obtaining your advice and feedback on the proposed rules.

Sincerely,

Michael R. Taylor
Deputy Commissioner for Foods
and Veterinary Medicine

Enclosure

Overview of Proposed Rulemakings Required by FSMA

- **Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food**

On January 4, 2013, FDA released for public comment the Preventive Controls for Human Food proposed rule that focuses on preventing problems that can cause foodborne illness. The proposed rule, which is required by the FDA Food Safety Modernization Act (FSMA), would apply to many domestic and foreign firms that manufacture, process, pack or hold human food. These firms would be required to have written plans that identify hazards, specify the steps that will be put in place to minimize or prevent those hazards, identify monitoring procedures and record monitoring results and specify what actions will be taken to correct problems that arise. FDA would evaluate the plans and continue to inspect facilities to make sure the plans are being implemented properly. Additional information on the Preventive Controls for Human Food proposed rule may be accessed at Docket No. FDA-2011-N-1920.

- **Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption**

On January 4, 2013, FDA also released for public comment its Produce Safety proposed rule to establish science-based standards for growing, harvesting, packing and holding produce on domestic and foreign farms. Section 105 of FSMA directs FDA to set science-based standards for the safe production and harvesting of fruits and vegetables that the Agency determines minimize the risk of serious adverse health consequences or death. FDA proposes to set standards associated with identified routes of microbial contamination of produce, including: (1) agricultural water; (2) biological soil amendments of animal origin; (3) health and hygiene; (4) animals in the growing area; and (5) equipment, tools and buildings. The proposed rule includes additional provisions related to sprouts.

The Produce Safety proposed rule covers most fruits and vegetables while they are in their raw or natural (unprocessed) state. It would not apply to raw agricultural commodities that are rarely consumed raw, those produced for personal or on-farm consumption, and (with certain documentation) those destined for commercial processing, such as canning, that will adequately reduce microorganisms of public health concern. Additional information on the Produce Safety proposed rule may be accessed at Docket No. FDA-2011-N-0921.

- **Foreign Supplier Verification Programs for Importers of Food for Humans and Animals**

On July 26, 2013, FDA issued for public comment the Foreign Supplier Verification Program proposed rule that would require importers to perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that is in compliance with FDA's preventive controls requirements and produce safety standards, where applicable, thus providing the same level of public health protection as that required of domestic food producers. Additional information on the proposed rule for Foreign Supplier Verification Programs may be accessed at Docket No. FDA-2011-N-0143.

- **Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications**

FDA issued the Third-Party proposed rulemaking on July 26, 2013, which establishes a program for accreditation of third-party auditors, also known as certification bodies, to conduct food safety audits and issue certifications of foreign facilities and the foods for humans and animals they produce. Importers will not generally be required to obtain certifications, but in certain circumstances the FDA may use certifications from accredited auditors in determine whether to admit certain imported food into the United States that the FDA has determined poses a food safety risk or in determining whether an importer is eligible to participate in a voluntary program for expedited review and entry of food. Additional information on the Third-Party proposed rule may be accessed at Docket No. FDA-2011-N-0146.

- **Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals**

FDA's proposed rule on Current Good Manufacturing Practices (CGMPs) and preventive controls for food for animals published on October 29, 2013. The proposed rule focuses on preventing problems in order to improve the safety of these products. The preventive controls provisions of the proposed rule, which are required by the FDA Food Safety Modernization Act, would apply to domestic and imported animal food, including pet food, animal feed, and raw materials and ingredients. Facilities producing animal food would be required to have written plans that identify hazards, specify the steps that will be put in place to minimize or prevent those hazards, identify monitoring procedures and record monitoring results, and specify what actions would be taken to correct problems that arise. The proposed rule would also establish certain Current Good Manufacturing Practices (CGMPs) that specifically address animal food. Additional information on the Preventive Controls for Animal Food proposed rule may be accessed at Docket No. FDA-2011-N-0922.

- **Focused Mitigation Strategies to Protect Food Against Intentional Adulteration**

FDA's proposed rule on intentional adulteration was published on December 24, 2013. The proposal would require domestic and foreign facilities to address vulnerable processes in their operations to prevent acts on the food supply intended to cause large-scale public harm. The proposed rule, which is required by the FDA Food Safety Modernization Act, would require the largest food businesses to have a written food defense plan that addresses significant vulnerabilities in a food operation. Comments on the proposed rule are due by June 30, 2014. Additional information on the Intentional Adulteration proposed rule may be accessed at Docket No. FDA-2013-N-1425.

- **Sanitary Transportation of Human and Animal Food**

FDA issued the Sanitary Transportation proposed rule on January 31, 2014. This proposed rule would require those who transport food to use sanitary transportation practices to ensure the safety of food. The proposed rule, which is required by the FDA Food Safety Modernization Act (FSMA), would help maintain the safety of both human and animal food during transportation by establishing criteria, e.g., conditions and practices, training and record keeping, for the sanitary transportation of food. Comments on the proposed rule are due by May 31, 2014. Additional information on the Sanitary Transportation proposed rule may be accessed at Docket No. FDA-2013-N-0013.