DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

September 12, 2013

Re: Request for tribal consultation on FDA Proposed Rules related to the Food Safety Modernization Act (FSMA)

Dear Tribal Leader:

On Monday, October 7, 2013, the U.S. Food and Drug Administration (FDA) will host a 2-hour webinar with tribal officials from 2:30 to 4:30 PM EDT to discuss FDA's proposed rule entitled "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food" (the Preventive Controls for Human Food proposed rule) and its rule entitled "Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption" (the Produce Safety proposed rule)—including our intent to prepare an Environmental Impact Statement (EIS)—and other regulations required by the FDA Food Safety Modernization Act (FSMA). This webinar is being held in response to requests for consultation by tribal officials, and Tribes are invited to share perspectives and any specific questions or concerns about these regulations.

The webinar will focus primarily on these two proposed rules, based on the expressions of interest we have received from tribal officials. It will also include information on FDA's intent to prepare an EIS to evaluate the potential environmental effects of the proposed Produce Safety proposed rule, which FDA announced on August 20, 2013. In addition, FDA will provide information and answer any questions about two other proposed rules required by FSMA that FDA published on July 26, 2013: "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals" (the Foreign Supplier Verification Program proposed rule) and "Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications" (the Third-Party proposed rule).

Michael Taylor, Deputy Commissioner for Foods and Veterinary Medicine, will discuss the four proposed rules. After the presentation, there will be an opportunity for participants to provide feedback and ask questions. Information on all four FSMA proposed rules noted above is included in the enclosure to this letter and is also available at http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm.

Webinar Instructions

- To join via internet (preferred): **https://collaboration.fda.gov/tribal/**
  - Click the URL above (or cut and paste it into your internet browser).
  - Click "Enter as a Guest" button, fill in your name, and then click "Enter Room."
  - You may listen to the webinar through your computer's speakers or by dialing in using the telephone access information below. Closed captioning will be available.
- Telephone Access: **1- 800-779-5741** / Passcode: **FDA**

Webinar Instant Replay
A replay of this teleconference call will be available about one hour after the call ends until November 15, 2013, by calling 1-888-567-0421 with passcode 58746.

Submitting Comments
We request your comments on the Preventive Controls for Human Food proposed rule (Docket No. FDA-2011-N-1920) and the Produce Safety proposed rule (Docket No. FDA-2011-N-0921) by November 15, 2013. We request your comments on the Foreign Supplier Verification Program proposed rule (Docket No. FDA-2011-N-0143) and the Third-Party proposed rule (Docket No. FDA-2011-N-0146) by November 26, 2013. You may submit comments, identified by the relevant docket number noted above, by any of the following methods:

- Electronic comment submissions
  - Follow the instructions for submitting comments on the Federal eRulemaking Portal at http://www.regulations.gov.
- Written comment submissions
  - Mail/hand delivery/courier (for paper or CD-ROM submissions) to Division of Dockets Management, HFA-305, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852

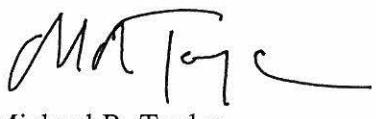
All submissions received must include the Agency name and relevant docket number. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided.

For access to the docket to read background documents or comments received, go to http://www.regulations.gov and insert the docket number(s) referenced above into the "Search" box and follow the prompts. Access can also be provided through the Division of Dockets Management at the address above.

If you have any questions regarding the webinar, please contact FDA's Tribal Liaison, Mary C. Hitch, Office of Health and Constituent Affairs, at 301-796-8639 or email mary.hitch@fda.hhs.gov.

I hope you are able to join us for this webinar with tribal officials, and I thank you for your interest in food safety.

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. As required by Section 302 of FSMA, the proposed rulemaking establishes a voluntary, user-fee funded voluntary qualified importer program to expedite entry into the United States of imported food from eligible, qualified importers. Additional information on the Third-Party proposed rule may be accessed at Docket No. FDA-2011-N-0146.