



January 18, 2023

Dear Tribal Leader:

The U.S. Food and Drug Administration (FDA or the Agency) is pleased to share the Fall 2022 Unified Agenda of Regulatory and Deregulatory Actions (Unified Agenda) to ensure that federally recognized Tribal Nations are aware of FDA's plans related to issuance of regulations and guidance documents. The Fall 2022 Unified Agenda, which was published in the Federal Register on January 4, 2023, is consolidated by the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget, and can also be found at <https://www.reginfo.gov/public/do/eAgendaMain>. FDA regulatory priorities are listed by Agency under the U.S. Department of Health and Human Services (HHS).

In the spring and fall of each year, the OIRA publishes the Unified Agenda which is a compilation of information about regulations under development by federal agencies, including FDA. In addition, the Regulatory Flexibility Act and Executive Order 12866 requires that executive agencies in the United States publish semiannual "regulatory flexibility agendas" that describe regulatory actions under development that will have significant effects on small businesses and other small entities (5 U.S.C. 602). FDA's Intergovernmental Affairs (IGA) team is here to assist tribal Nations/governments/officials, including the associations representing them, on FDA-related matters. Please feel free to contact Paul Allis, Senior Intergovernmental Affairs Specialist for Tribal Affairs, at paul.allis@fda.hhs.gov or FDA's IGA staff at IGA@fda.hhs.gov, if you have any questions on the Unified Agenda or need assistance with any FDA-related issue.

We look forward to continuing to strengthen the relationship between FDA and federally recognized Tribal Nations as the Agency continues to work to fulfill its mission to protect and advance the public health.

Sincerely,

Nicholas D. Alexander, J.D.
Director, Intergovernmental Affairs

