

7/29/2024

Dear Tribal Leader:

The U.S. Food and Drug Administration (FDA) is pleased to share the Spring <u>2024 Unified Agenda of</u> <u>Regulatory and Deregulatory Actions (Unified Agenda)</u> to ensure that federally recognized Tribal Nations are aware of FDA's plans related to issuance of regulations. The Spring 2024 Unified Agenda, which was published on July 5, 2024, is consolidated by the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB). FDA's planned regulatory actions are listed by Agency and can be found under the U.S. Department of Health and Human Services (HHS).

In the fall and spring of each year, OIRA publishes the Unified Agenda, which is a compilation of information about regulations under development in the near and long term by federal agencies, including FDA. The purpose of the Unified Agenda is to encourage transparency and more effective public participation in the regulatory process. In addition, the Regulatory Flexibility Act (5 U.S.C. 602) and Executive Order 12866 require that executive agencies in the U.S. publish semiannual "regulatory flexibility agendas" that describe regulatory actions under development that will have significant effects on small businesses and other small entities. The Unified Agenda helps agencies fulfill these requirements.

FDA's Intergovernmental Affairs team is here to assist state/local/territorial/tribal officials, including the associations representing them, on FDA policy-related matters. Please feel free to contact Paul Allis, Senior Intergovernmental Affairs Specialist for Tribal Affairs at <u>paul.allis@fda.hhs.gov</u> or FDA's IGA staff at <u>IGA@fda.hhs.gov</u>, if you have any questions.

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 of Americans, including the public health of American Indian and Alaskan Native Tribes and individuals in American Indian and Alaskan Native Communities.

Sincerely,

Lauren Roth Associate Commissioner for Policy Office of Policy Office of the Commissioner U.S. Food and Drug Administration