



FDA Tribal Listening Session on the “*Safe Disposal of Opioid Analgesics*” Summary

Background

On October 5, 2023, FDA Intergovernmental Affairs and Center for Drug Evaluation and Research (CDER) hosted a listening session with federally recognized American Indian and Alaska Native tribes on the safe disposal of opioid analgesics. FDA is seeking additional tribal input and comments to the [Agency’s April 2023 announcement](#) requiring manufacturers of opioid analgesics dispensed in outpatient settings to make prepaid mail-back envelopes available to outpatient pharmacies and other dispensers as an additional opioid disposal option for patients. Tribal officials have been provided an opportunity to provide written comment to Docket No. [FDA-2023-N-0917](#). CDER also extended the comment period and the docket remained open through November 2023. These additional opportunities were announced in an FDA Dear Tribal Leader Letter dated August 31, 2023.

Summary

FDA is seeking [information and comments](#) from tribal governments and/or their designees on In-Home Disposal Systems for Opioid Analgesics. In April 2023, FDA announced that it had established a [docket](#) to obtain information and comments that will assist the Agency in assessing whether in-home disposal products can be expected to meet the public health goal of mitigating the risk of nonmedical use or overdose if the Agency were to require drug manufacturers to make in-home disposal products available to patients under a REMS.

There were 57 registrants, including Tribal officials, Tribal community members, Tribal public health representatives, for the virtual Tribal listening session. Paul Allis, Senior Intergovernmental Affairs Specialist opened the Tribal listening session with a welcome and announcements regarding the session proceedings and meeting expectations. Mr. Allis also acknowledged the unique government-to-government relationship that federally recognized tribes have with the federal government and reaffirmed FDA’s commitment to robust and meaningful consultation with Tribes. He then opened the discussion to Dr. Marta Sokolowska, Deputy Center Director for Substance Use and Behavioral Health, Center for Drug Evaluation and Research, discussed the [Agency’s April 2023 announcement](#) requiring manufacturers of opioid analgesics dispensed in outpatient settings to make prepaid mail-back envelopes available to outpatient pharmacies and other dispensers as an additional opioid analgesic disposal option

for patients. Dr. Sokolowska also discussed FDA's broader approach to expanding additional at home disposal and ensure equitable access for patients, pharmacies, and communities.

Following FDA's presentation, there was a question and answer session. Paul Allis, FDA Intergovernmental Affairs, opened the listening session for questions from attendees. No questions or comments were received; however, tribal leader and/or their designees were encouraged to make additional comments to the docket. The listening session was concluded. read questions submitted by attendees in the chat portion of the Zoom meeting. Several questions

Next Steps

FDA subsequently posted a [recording of the tribal listening session](#) on our website and shared it with registrants. FDA will post a copy of the tribal listening session transcript to the docket. FDA is accepting comments to the docket through November 6, 2023. and will continue to monitor the docket for additional comments from Tribal officials.