9/1/2023

Dear Tribal Leader:

The U.S. Food and Drug Administration (FDA) is hosting a listening session with federally recognized American Indian and Alaska Native tribes on the safe disposal of opioid analgesics.

FDA invites you and/or your designated representative(s) to participate in this one-hour listening session through an all tribes' call on **Thursday, October 5, 2023, at 2pm EST**. FDA will discuss 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. We will also discuss FDA's broader approach to expanding additional at home disposal and ensure equitable access for patients, pharmacies, and communities. Agency representatives will also answer questions, and receive tribal feedback. A transcript of the listening session will be added to the FDA Tribal Affairs webpage and a recording of the listening session discussion will be available after the call.

Listening Session Call Information:
Thursday, October 5, 2023, at 2pm EST
To participate in the call, you must register via the link here.[1]

In addition, 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.

FDA welcomes your written comments. Comments on the "In-Home Disposal Systems for Opioid Analgesics; Request for Information" should be submitted to Docket No. FDA-2023-N-0917. The commenting period closed on August 28, 2023; however, following our stakeholder meeting, the Agency will reopen the docket for 30 days should you have additional comments.

Comments on this docket must be submitted to FDA using any of the following methods:

- Electronic submissions: Follow the instructions for submitting comments on the Federal eRulemaking Portal at http://www.regulations.gov.

[1] https://fda.zoomgov.com/meeting/register/vJItcempqj8rHDzmKdVKKMirV6b5LPTynzE

- Written submissions via Mail/Hand delivery/Courier: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Received comments will be placed in the docket and publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

If you have any questions regarding the docket please contact Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration at Kimberly.Lehrfeld@fda.hhs.gov.

FDA's Intergovernmental Affairs (IGA) team is available to assist tribal officials for all FDA inquiries and can be reached via email at IGA@fda.hhs.gov. For more information regarding FDA's activities with federally recognized tribal governments, including FDA's Dear Tribal Leader Letters, please visit www.fda.gov/tribal or contact the IGA staff.

I hope you can join us for the tribal listening session call on Thursday, October 5, 2023. We look forward to continuing to strengthen the relationship between FDA and tribal governments as the Agency fulfills its mission to protect and promote public health.

Sincerely,

Marta Sokolowska

Marta Sokolowska, Ph.D.
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