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Adam Krantz

April 6, 2026

Dockets Management Staff
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
Submitted via www.regulations.gov

RE: Developing Specifications for In-Home Disposal Systems for Opioid Analgesics Dispensed in an Outpatient Setting; Establishment of a Public Docket; Request for Comments (Docket No. FDA-2026-N-1001)

The National Association of Clean Water Agencies (NACWA) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) consideration of specifications for in-home disposal systems for unused prescriptions under the Opioid Analgesic Risk Evaluation and Mitigation Strategy (OA REMS). FDA is asking for comments on what would be necessary to show that these systems may mitigate the serious risks of abuse or overdose involving these medications (91 FR 11077). NACWA asks FDA to also consider the potential environmental impacts of these in-home disposal systems.

NACWA represents the interests of 360 publicly owned wastewater treatment agencies nationwide, serving the majority of the sewered population in the U.S. NACWA member utilities are responsible for treating the millions of gallons of wastewater produced by their communities each day. Many NACWA members are actively involved in efforts to reduce the quantities of potential pollutants, such as pharmaceuticals, that are discharged into the sewer system. This is especially important for the growing number of utilities that are providing recycled water to their communities.

NACWA has communicated in the past with the FDA, the Environmental Protection Agency (EPA), and the Drug Enforcement Administration (DEA) on the need for more practical disposal options to reduce flushing or down-the-drain disposal of pharmaceuticals into the sewer system. NACWA and its members have long supported pharmaceutical take-back programs for unused prescription medications. NACWA has participated in EPA's National Water Reuse Plan (WRAP) Action 2.9 to *Align Tools to Promote Best Management of Unused/Expired Pharmaceuticals* to improve communication about take-back programs. Mail-back envelopes are an effective part of take-back programs, allowing destruction of the pharmaceuticals by incineration. Disposal by flushing is not environmentally protective, since wastewater treatment plants

are not designed to remove pharmaceuticals. Disposing of pharmaceuticals in the trash is also not environmentally protective, since pharmaceuticals are found in the landfill leachate that may be discharged to a wastewater treatment plant.

NACWA supported FDA's 2023 modification to the OA REMS to require that prepaid mail-back envelopes be made available to outpatient pharmacies and other dispensers as an additional disposal option for patients. Although take-back programs may be available at pharmacies and other locations in some areas, the additional convenience of free mail-back envelopes provided with prescriptions may increase the likelihood that unused opioid medications will be disposed of properly, especially for people with medical conditions that make it difficult to leave their homes. Mail-back envelopes provide a safe and convenient disposal option for unused opioid medications, helping to reduce illicit drug use and protect the environment.

NACWA is concerned that in-home disposal systems may not provide adequate destruction of opioids or other pharmaceuticals. While the in-home disposal systems may provide enough destruction to prevent illicit drug use, the in-home disposal systems will still be placed in the trash, and the pharmaceutical compounds may ultimately end up in landfill leachate before being discharged to a wastewater utility. NACWA therefore supports existing take-back options – including kiosks in pharmacies, community take-back events, or mail-back envelopes – over in-home disposal systems since this method is less protective of the environment.

NACWA urges FDA to continue emphasizing that take-back options are the preferred method for disposing of unused opioids. If FDA determines that in-home disposal systems will help mitigate illicit drug use in certain situations, NACWA asks that FDA emphasize these specific situations, and make clear that in-home disposal systems should be an *additional* option to prevent illicit drug use in these situations – rather than supplanting the established, highly protective options of pharmacy and community take-back and mail-back approaches. NACWA supports FDA's planned identification of appropriate specifications for these systems, since they are not currently regulated by any federal agency.

In sum, NACWA asks that FDA consider the environmental impacts of the in-home disposal systems along with their ability to mitigate illicit drug use and detail the specific situations when in-home disposal systems might be preferred. NACWA also requests that educational materials provided with the in-home disposal systems include information on take-back disposal options and why they are preferred.

Thank you for your consideration of these comments. Please contact me at 202-533-1836 or cfinley@nacwa.org if you have any questions.

Sincerely,



Cynthia A. Finley, Ph.D.
Director, Regulatory Affairs