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Dockets Management Staff

Food and Drug Administration

5630 Fishers Lane, Room 1061

Rockville, MD 20852

Submitted via www.regulations.gov

**RE: Providing Mail-Back Envelopes and Education on Safe Disposal With
Opioid Analgesics Dispensed in an Outpatient Setting (Docket No. FDA-
2022-N-0165)**

The National Association of Clean Water Agencies (NACWA) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) potential modification to the Opioid Analgesic Risk Evaluation and Mitigation Strategy (OA REMS) to require mail-back envelopes and education on safe disposal for opioid analgesics dispensed in an outpatient setting (87 FR 23869). NACWA supports this modification, since it will provide a safe and convenient disposal option for unused opioid medications, helping to reduce illicit drug use and protect the environment.

NACWA represents the interests of 350 publicly owned wastewater treatment agencies nationwide, serving the majority of the sewered population in the US. 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 their communities with recycled water.

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. 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 plant 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.

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. NACWA recommends that envelopes be given on request at pharmacies in case the envelope that was originally dispensed with a prescription is lost. If FDA determines that mail-back envelopes will only be required for opioid prescriptions for acute or one-time use, rather than for chronic conditions, NACWA recommends that envelopes be provided to anyone upon request. Patients with chronic conditions may still have circumstances leading to unused opioid medications, such as when a change in prescription is made before the current one is completed. NACWA also requests that educational materials provided with the envelopes include information on other disposal options, in case the recipient does not want to use the mail-back envelope or needs to dispose of other medications.

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,

A handwritten signature in black ink, reading "Cynthia A. Finley". The signature is fluid and cursive, with the first name "Cynthia" being the most prominent part.

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