



June 21, 2022

Lauren K. Roth
Associate Commissioner, Office of Policy
Food and Drug Administration
U.S. Department of Health and Human Services
5901-B Ammendale Road
Building 32, Room 4232
Beltsville, MD 20705

Re: FDA-2022-N-0165, Providing Mail-Back Envelopes and Education on Safe Disposal with Opioid Analgesics Dispensed in an Outpatient Setting

Dear Associate Commissioner Roth,

The Association of Metropolitan Water Agencies (AMWA) is pleased to have the opportunity to provide comment on potential modifications to the Opioid Analgesic Risk Evaluation and Mitigation Strategy (OA REMS). These potential modifications would require outpatient providers of opioid analgesics to provide recipients with mail-back envelopes and education on safe disposal methods for leftover drugs.

AMWA is an organization of the general managers and CEOs of large publicly owned drinking water utilities. Members serve communities of more than 100,000 people to provide safe, clean drinking water to the public. The association strongly supports the provision of mail-back envelopes and disposal education materials when opioids are dispensed and asks the administration to continue using its authorities to promote the proper disposal of these pharmaceutical products.

AMWA is pleased the Food and Drug Administration (FDA) is acting to address the public health implications of excess medications. In addition to addressing nonmedical use and accidental exposure, the proposed action could help reduce pharmaceutical residues found in the water environment that are a significant concern for drinking water utilities. Reducing the opportunities for entry of these pharmaceuticals into waste streams will reduce their concentration in drinking water sources, which will serve to reduce contamination both from today's pharmaceuticals and those developed in the future.

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Minimizing pharmaceutical loading by utilizing take-back programs is one step that will in turn help reduce pharmaceutical concentrations in treated drinking water. AMWA has long supported a national program to provide consumers with an easy and secure method to dispose of unused prescriptions. The association believes mail-back options are a better solution than flushing unused medications, even those on the approved FDA “flush list,” because flushing directly introduces these pharmaceuticals into the water environment. This proposed action is a crucial first step to reducing the amount of unused opioid analgesics, and FDA should continue this practice with other pharmaceutical drugs.

AMWA further supports continued research into better understanding the human health risks of pharmaceuticals, including exposure at low concentrations. AMWA urges FDA and other federal agencies to continue to address the issue of pharmaceuticals in waters through coordination of activities and focusing research on treatment technologies, risk assessment, fate and transport, and effective communication.

AMWA thanks the administration for its efforts to protect public health by proposing to provide mail-back envelopes and education materials on disposal of unused pharmaceuticals. If you have any questions, please contact AMWA’s Manager of Regulatory and Scientific Affairs, Brian Redder (Redder@amwa.net).

Sincerely,

A handwritten signature in black ink, appearing to read "Thomas Dobbins". The signature is fluid and cursive, with the first name being the most prominent.

Thomas Dobbins
Chief Executive Officer

cc: Patrick Raulerson, FDA