Dear Healthcare Provider Letter #1

FDA-Required REMS for Serious Drug Risks

Risk Evaluation and Mitigation Strategy (REMS) for opioid analgesic drug products[1] used in the outpatient setting to address their risks of addiction, abuse, and misuse, which can lead to overdose and death.

Dear Healthcare Provider:

You are receiving this letter because you are either registered with the Drug Enforcement Administration (DEA) to prescribe Schedule II, III, IV opioid analgesics and/or you are involved in the management or support of patients with pain and their caregivers. The purpose of this letter is to inform you about an important upcoming change to the Opioid Analgesic REMS that is required by the U.S. Food and Drug Administration (FDA) for opioid analgesic drug products[1] used in the outpatient setting.

By March 31, 2025 the Opioid Analgesic REMS Program Companies will be required to provide pre-paid drug mail-back envelopes upon request to pharmacies and other dispensers that dispense opioid analgesics for outpatient use.

Counseling patients on the options for safe disposal of unused opioid analgesics is an important component of the Opioid Analgesic REMS to avoid nonmedical use, opioid use disorder (OUD), and overdose. In addition to pre-paid drug mail-back envelopes, other disposal options include drug take-back sites or programs. If these options are not available, the next best option is for patients to immediately flush their opioid analgesics down the toilet. More information on safe disposal methods is available at: www.fda.gov/safe-disposal-medicines.

More information about this REMS can be obtained at: www.opioidanalgesicrems.com or by calling the Opioid Analgesic REMS Call Center at 1-800-503-0784.

Sincerely,
The Opioid Analgesic REMS Program Companies

[1]**The branded and generic drug products subject to this REMS include *all*:** a) oral dosage forms of extended-release and immediate-release opioids containing: codeine and codeine analogs, hydrocodone, hydromorphone, levorphanol, meperidine, morphine, oxycodone, oxymorphone, pentazocine, tapentadol and tramadol; b) fentanyl, butorphanol and buprenorphine-containing intranasal, buccal and transdermal delivery systems; and c) methadone tablets and solutions that are indicated for use as analgesics.