

**FOOD AND DRUG ADMINISTRATION (FDA)**  
**Center for Drug Evaluation and Research (CDER)**

***Joint Meeting of the Drug Safety and Risk Management Advisory Committee (DSaRM)***  
***and the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC)***

May 5, 2025

**DRAFT QUESTIONS**

---

---

1. **DISCUSSION:** Discuss your interpretation of the estimates of the incidence and prevalence of misuse, abuse, and Opioid Use Disorder (OUD) in patients using Opioid Analgesics (OAs) long-term (PMR 3033-1).

Please also comment on factors influencing your interpretation, e.g.,

- Study strengths and limitations
- Definitions and measurements of these outcomes, including the two different definitions of OUD (i.e., DSM-5-OUD, pain-adjusted DSM-5-OUD)
- Generalizability of findings and relevance to patients currently using OAs given the evolving opioid landscape
- Consistency of findings with other available evidence or clinical experience

2. **DISCUSSION:** Discuss your interpretation of the estimates of the incidence of fatal and nonfatal overdose in patients using OAs long-term (PMR 3033-2).

Please also comment on factors influencing your interpretation, e.g.,

- Study strengths and limitations
- Ascertainment of opioid overdose and any potential for bias
- Heterogeneity of results across study populations, particularly those with Medicaid versus commercial insurance
- Generalizability of findings and relevance to patients currently using OAs given the evolving opioid landscape
- Consistency of findings with other available evidence or clinical experience

3. **DISCUSSION:** Discuss your interpretation of the risk factor analyses in PMRs 3033-1 and 3033-2 and what you see as the most important findings. Please consider:
- The study designs and analytic approaches
  - Consistency of findings with other available evidence or clinical experience

In particular, please comment on the study results related to dose and formulation (ER/LA versus IR/SA).

4. **DISCUSSION:** Given your interpretation of the findings from these studies and what is currently in FDA-approved OA labeling, are there any novel findings that you believe FDA should communicate to healthcare providers, patients, and other members of the public?