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

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?