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 AGENDA

The Committees will discuss the findings of the completed extended-release/long-acting opioid analgesic (ER/LA OA) postmarketing requirements (PMRs) 3033-1 and 3033-2. These PMRs are prospective (3033-1) and retrospective (3033-2) epidemiologic studies that examined the serious risks and predictors of misuse, abuse, addiction, and fatal and non-fatal opioid overdose in patients with long-term use of opioid analgesics for management of chronic pain, including patients prescribed ER/LA OAs.

8:00 a.m.	Call to Order and Introduction of Committee	**Brian T. Bateman, MD, MSc** Chairperson, AADPAC
8:05 a.m.	Conflict of Interest Statement	**Jessica Seo, PharmD** Designated Federal Officer, DSaRM
8:10 a.m.	FDA Opening Remarks	**Leah Crisafi, MD, FASA** Commander, US Public Health Service Director Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP), Office of Neuroscience Office of New Drugs, CDER, FDA
8:15 a.m.	Regulatory Background and the Evolving Opioid Landscape	**Jana McAninch, MD, MPH, MS** Associate Director for Public Health Initiatives Office of Surveillance and Epidemiology (OSE) CDER, FDA
8:45 a.m.	**INDUSTRY PRESENTATIONS**	**Opioid PMR Consortium (OPC)**
	Opioid PMR Consortium Introduction and PMR Overview	**Alexander M. Walker, MD, DrPH** Adjunct Professor, Epidemiology, Harvard T.H. Chan School of Public Health
	Study 3033-1 - Incidence or Prevalence of and Risk Factors for Developing Prescription Opioid Misuse, Abuse or Addiction Among Patients Prescribed Long-term Opioid Therapy	**Bobbi Jo Yarborough, PysD** Senior Investigator, Kaiser Permanente Northwest Center for Health Research
	Study 3033-2 - Incidence and Prognostic Factors for Opioid-involved Overdose or Opioid Overdose-Related death (OOD)	**John D. Seeger, PharmD, PsyD** Vice President for Epidemiology, RTI-HS Adjunct Assistant Professor, Epidemiology, Harvard T.H. Chan School of Public Health

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DRAFT AGENDA (cont.)

	INDUSTRY PRESENTATIONS (CONT.)	
	Conclusions	**Alexander M. Walker, MD, DrPH**
10:15 a.m.	Clarifying Questions	
10:30 a.m.	**BREAK**	
10:45 a.m.	**FDA PRESENTATIONS**	
	Key Methodological and Statistical Considerations for ER/LA OA PMR Studies 3033-1 and 3033-2	**Hana Lee, PhD** Staff Fellow Division of Biometrics VII (DB-VII) Office of Biostatistics (OB) Office of Translational Sciences (OTS), CDER, FDA
	Key Study Findings and Interpretation of ER/LA OA PMR Studies 3033-1 and 3033-2	**Cynthia Kornegay, PhD** Epidemiologist Division of Epidemiology II (DEPI-II) Office of Pharmacovigilance and Epidemiology (OPE) OSE, CDER, FDA
11:55 a.m.	Clarifying Questions	
12:10 p.m.	**LUNCH**	
1:00 p.m.	**OPEN PUBLIC HEARING**	
2:00 p.m.	Charge to the Committee	**Jana McAninch, MD, MPH, MS**
2:05 p.m.	Questions to the Committee/Committee Discussion	
3:30 p.m.	**BREAK**	
3:45 p.m.	Questions to the Committee/Committee Discussion (cont.)	
5:00 p.m.	**ADJOURNMENT**	