

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

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, PsyD
Senior Investigator,
Kaiser Permanente 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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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**