

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)***
September 10-11, 2020

MEETING AGENDA

The committees will discuss the results of required postmarketing studies (Postmarketing Requirements 3051-1, 3051-2, 3051-3, and 3051-4) that evaluated the effect of the reformulation of OXYCONTIN (oxycodone hydrochloride extended-release tablets, manufactured by Purdue Pharma L.P., NDA 022272) on abuse, misuse, and fatal and non-fatal overdose, associated with OXYCONTIN. The committees will discuss whether these studies, in concert with other information from the published literature, have demonstrated that the reformulated OXYCONTIN product has resulted in a meaningful reduction in these outcomes. The committees will also discuss the broader public health impact of OXYCONTIN's reformulation.

Day 1: Thursday, September 10, 2020

9:00 a.m.	Call to Order	Sonia Hernandez-Diaz, MD, MPH, DrPH Chairperson, DSaRM
9:05 a.m.	Introduction of Committee and Conflict of Interest Statement	Philip Bautista, PharmD Designated Federal Officer, DSaRM
9:20 a.m.	FDA Opening Remarks	Patrizia Cavazzoni, MD Acting Director, CDER, FDA
9:30 a.m.	OSE Introductory Remarks	Judy Staffa, PhD, RPh Associate Director for Public Health Initiatives Office of Surveillance and Epidemiology (OSE) CDER, FDA
9:40 a.m.	In Vitro, Pharmacokinetic and Human Abuse Potential Evaluation of the Deterrent Properties of Reformulated OxyContin	Silvia Calderon, PhD Senior Pharmacologist Controlled Substance Staff Office of the Center Director, CDER, FDA
9:50 a.m.	Reformulated OxyContin: Regulatory History of the Postmarketing Requirements (PMRs)	Mark Liberatore, PharmD, RAC LCDR, United States Public Health Service (USPHS) Deputy Director for Safety Division of Anesthesiology, Addiction Medicine and Pain Medicine (DAAP) Office of Neuroscience (ON) Office of New Drugs (OND), CDER, FDA
10:00 a.m.	A Systems Approach to Considering the Impacts of OxyContin Abuse Deterrent Formulation	Sara Eggers, PhD Director, Decision Support and Analysis Team Office of Program and Strategic Analysis (OPSA) Office of Strategic Programs (OSP), CDER, FDA

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MEETING AGENDA (cont.)

10:15 a.m. **GUEST SPEAKER PRESENTATION**

Overview of Evaluating ADFs in the
Community

Nabarun Dasgupta, MPH, PhD
Senior Scientist
Injury Prevention Research Center
University of North Carolina at Chapel Hill

10:35 a.m. Clarifying Questions

10:45 a.m. **BREAK**

11:00 a.m. **SPONSOR PRESENTATIONS**

Introduction

Purdue Pharma, L.P.

Craig Landau, MD
President and Chief Executive Officer
Purdue Pharma L.P.

Overview and Results of Postmarketing
Studies 1-4

Alexander M. Walker, MD, DrPH
Principal
World Health Information Science Consultants

12:15 p.m. **LUNCH**

1:15 p.m. **SPONSOR PRESENTATIONS (cont.)**

Real World Evidence for Opioid Analgesics
with Abuse Deterrent Properties

Richard C. Dart, MD, PhD
Director, Rocky Mountain Poison and Drug Safety
Executive Director, RADARS System
Professor, University of Colorado School of Medicine

Closing Remarks

Craig Landau, MD

2:00 p.m. Clarifying Questions

2:30 p.m. **FDA PRESENTATIONS**

Utilization Patterns of Oxycodone Extended-
Release Products

Nabila Sadiq, PharmD, MPH
Drug Utilization Analyst
Division of Epidemiology II (DEPI-II)
Office of Pharmacovigilance and Epidemiology (OPE)
OSE, CDER, FDA

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MEETING AGENDA (cont.)

FDA PRESENTATIONS (cont.)

Methodologic Considerations for Design and Interpretation of Reformulated OxyContin Postmarketing Studies **Hana Lee, PhD**
Staff Fellow
Division of Biometrics VII (DB-VII)
Office of Biostatistics (OB)
Office of Translational Sciences (OTS), CDER, FDA

3:10 p.m. **BREAK**

3:25 p.m. **FDA PRESENTATIONS (cont.)**

FDA Review of PMR 3051-1 & 3051-3: Treatment Center Data to Assess the Impact of OxyContin Reformulation on Non-Oral and Overall Abuse of OxyContin **Celeste Mallama, PhD, MPH**
Epidemiologist
DEPI-II, OPE, OSE, CDER, FDA

FDA Review of PMR 3051-2 & 3051-4: Poison Control Center Study and Opioid Overdose Study Using Administrative Claims Data **Alex Secora, PhD**
Epidemiologist
DEPI-II, OPE, OSE, CDER, FDA

4:25 p.m. Clarifying Questions

5:00 p.m. **ADJOURNMENT**

Day 2: Friday, September 11, 2020

9:00 a.m. Call to Order and Introduction of Committee **Sonia Hernandez-Diaz, MD, MPH, DrPH**
Chairperson, DSaRM

9:05 a.m. Introduction of Committee **Philip Bautista, PharmD**
Designated Federal Officer, DSaRM

9:15 a.m. FDA Introductory Remarks **Judy Staffa, PhD, RPh**

9:25 a.m. **NATIONAL INSTITUTE ON DRUG ABUSE (NIDA) PRESENTATION**

U.S. Opioid Crisis **Wilson Compton, MD, MPE**
Deputy Director, NIDA

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MEETING AGENDA (cont.)

9:45 a.m. Clarifying Questions

9:55 a.m. **FDA PRESENTATIONS**

Literature Review: Impact of Reformulated
OxyContin on Abuse and Opioid-related
Morbidity and Mortality

Christina Greene, PhD
Epidemiologist
DEPI-II, OPE, OSE, CDER, FDA

10:20 a.m. FDA Summary of Postmarketing Findings on
OxyContin ADF Effectiveness and Public
Health Impact

Jana McAninch, MD, MPH, MS
Senior Medical Epidemiologist
DEPI-II, OPE, OSE, CDER, FDA

10:50 a.m. Clarifying Questions

11:15 a.m. **LUNCH**

12:00 p.m. **OPEN PUBLIC HEARING**

2:00 p.m. Charge to the Committee

Judy Staffa, PhD, RPh

2:05 p.m. Questions to the Committee/Committee Discussion

3:00 p.m. **BREAK**

3:15 p.m. Questions to the Committee/Committee Discussion (cont.)

5:00 p.m. **ADJOURNMENT**