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

DRAFT 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 and Introduction of Committee	**Sonia Hernandez-Diaz, MD, MPH, DrPH** Chairperson, DSaRM
9:15 a.m.	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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DRAFT 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**	**Purdue Pharma, L.P.**
	Introduction	**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
12:00 p.m.	**LUNCH**	
1:00 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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DRAFT 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
9:15 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
9:45 a.m.	Clarifying Questions	

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DRAFT AGENDA (cont.)

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**	