FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Psychopharmacologic Drugs Advisory Committee (PDAC) and the Drug Safety and Risk Management Advisory Committee (DSaRM)
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
October 31, 2017

DRAFT AGENDA

The committees will discuss new drug application (NDA) 209819 buprenorphine subcutaneous injection, submitted by Indivior, Inc., for the treatment of opioid dependence.

8:00 a.m.	Call to Order and Introduction of Committee	**Raj Narendran, MD** Acting Chairperson, PDAC
8:05 a.m.	Conflict of Interest Statement	**Kalyani Bhatt, MS** Designated Federal Officer, PDAC
8:10 a.m.	FDA Opening Remarks	**Celia Winchell, MD** Clinical Team Leader Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) Office of Drug Evaluation II (ODE II) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	**APPLICANT PRESENTATIONS**	**Indivior, Inc.**
	Introduction Medicines Development Program RBP-6000	**Susan Learned, MD, PharmD, PhD** Senior Vice-President of Global Medicines Development, Indivior Inc.
	Need for Improvements In the Treatment of Opioid Use Disorder	**Brent Boyett, DO, DMD** Boyett Health Services Inc.
	Clinical Pharmacology, RBP-6000	**Celine Laffont, PhD** Director, Quantitative Clinical Pharmacology Indivior Inc.
	Clinical Efficacy, RBP-6000	**Barbara Haight, PharmD** Medicines Development Lead and Senior Director RBP-6000, Indivior Inc.
	Clinical Safety, RBP-6000	**Anne Andorn, MD** Head Late Stage Clinical Development Indivior Inc
	Clinical Perspective	**Eric C. Strain, MD** Director, John Hopkins Center for Substance Abuse Treatment and Research, John Hopkins University

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DRAFT AGENDA (cont.)

9:45 a.m.	Clarifying Questions	
10:00 a.m.	**BREAK**	
10:15 a.m.	**FDA PRESENTATIONS**	
	Clinical Overview	**Emily Deng, MD, MPH** Clinical Reviewer DAAAP, ODEII, OND, CDER, FDA
	Blockade Study: Analyses and Issues	**Alan Trachtenberg, MD, MPH** Clinical Reviewer Controlled Substance Staff, OND, CDER, FDA **Wei Liu, PhD** Statistics Reviewer Division of Biostatistics VI, Office of Biostatistics (OB) Office of Translational Sciences (OTS), CDER, FDA
	Blockade Study: Pharmacokinetic-Pharmacodynamic Analyses of Drug Liking	**Michael Bewernitz, PhD** Pharmacometrics Reviewer Division of Pharmacometrics Office of Clinical Pharmacology, OTS, CDER, FDA
	Clinical and Statistical Review	**Feng Li, PhD** Statistics Reviewer Division of Biostatistics II, OB, OTS, CDER, FDA **Emily Deng, MD, MPH**
	Proposed Risk Evaluation and Mitigation Strategies (REMS) for RBP-6000	**Somya Dunn, MD** RISK Management Analyst Division of Risk Management Office of Surveillance and Epidemiology, CDER, FDA
11:40 a.m.	Clarifying Questions	
12:00 p.m.	**LUNCH**	
1:00 p.m.	**OPEN PUBLIC HEARING**	

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DRAFT AGENDA (cont.)

2:00 p.m.	Charge to the Committe	**Sharon Hertz, MD** Director DAAAP, ODEII, OND, CDER, FDA
2:10 p.m.	Questions to the Committee/Committee Discussion	
3:15 p.m.	**BREAK**	
3:30 p.m.	Questions to the Committee/Committee Discussion (cont.)	
5:00 p.m.	**ADJOURNMENT**	