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 (DSaRM) Advisory Committee
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
November 1, 2018

AGENDA

The committees will discuss efficacy, safety and risk-benefit profile of new drug application (NDA) 210417, buprenorphine and samidorphan sublingual tablets, submitted by Alkermes, Inc., for adjunctive treatment of major depressive disorder.

8:00 a.m.	Call to Order and Introduction of Committee	**Raj Narendran, MD** Chairperson, PDAC
8:05 a.m.	Conflict of Interest Statement	**Kalyani Bhatt, BS, MS** Designated Federal Officer, PDAC
8:10 a.m.	FDA Opening Remarks	**Mitchell Mathis, MD** Director Division of Psychiatry Products (DPP) Office of Drug Evaluation I (ODE I) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	**APPLICANT PRESENTATIONS**	**Alkermes, Inc.**
	Introduction	**Lisa von Moltke, MD** Senior Vice President, Clinical Development Alkermes, Inc.
	The Unmet Need in MDD, and Challenges in MDD Clinical Trials	**George Papakostas, MD** Harvard Medical School Massachusetts General Hospital
	Clinical Efficacy	**Jerald Schindler, DrPH** Vice President, Biostatistics Alkermes, Inc.
	Clinical Safety, and Risk Mitigation Strategies	**Gary Bloomgren, MD** Vice President, Drug Safety and Pharmacovigilance Alkermes, Inc.
	Clinical Perspective and Benefit-Risk Profile	**Sanjay Mathew, MD** Baylor College of Medicine
	Conclusion	**Lisa von Moltke, MD**

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9:45 a.m.	Clarifying Questions to Applicant	
10:15 a.m.	**BREAK**	
10:30 a.m.	**FDA PRESENTATIONS**	
	Regulatory History	**Tiffany Farchione, MD** Deputy Director DPP, ODE I, OND, CDER, FDA
	Clinical Efficacy and Safety Overview	**Semhar Ogbagaber, PhD** Statistician Division of Biometrics I Office of Biostatistics Office of Translational Sciences, CDER, FDA
		Daniel J. Lee, MD Clinical Reviewer DPP, ODE I, OND, CDER, FDA
	Abuse Potential of Buprenorphine/Samidorphan (BUP/SAM)	**Edward Hawkins, PhD** Pharmacologist Controlled Substance Staff Office of the Center Director, CDER, FDA
	FDA Review of the Epidemiologic and Surveillance Data	**Celeste Mallama, PhD, MPH** Epidemiologist Division of Epidemiology II Office of Surveillance and Epidemiology (OSE) CDER, FDA
	UNIVERSITY OF WASHINGTON MEDICAL SCHOOL DEPARTMENT OF PSYCHIATRY & BEHAVIORAL SCIENCES PRESENTATION	
	Depression Effects On Long-Term Prescription Opioid Use, Abuse and Addiction	**Mark Sullivan, MD, PhD** Professor, Psychiatry and Behavioral Sciences University of Washington Medical Center
	FDA PRESENTATIONS (cont.)	
	Risk Management for Buprenorphine/Samidorphan	**Somya Dunn, MD** Commander, United States Public Health Service Risk Management Analyst Division of Risk Management, OSE, CDER, FDA

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12:00 p.m.	Clarifying Questions to FDA and Dr. Sullivan	
12:15 p.m.	**LUNCH**	
1:15 p.m.	**OPEN PUBLIC HEARING**	
2:15 p.m.	Charge to Committee	**Mitchell Mathis, MD**
2:25 p.m.	Questions to the Committee/Committee Discussion	
3:20 p.m.	**BREAK**	
3:30 p.m.	Questions to the Committee/Committee Discussion (cont.)	
5:00 p.m.	**ADJOURNMENT**	