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
October 9, 2020

DRAFT AGENDA

The committees will discuss the efficacy, safety, and benefit-risk profile of new drug application (NDA) 213378, olanzapine/samidorphan oral tablets, submitted by Alkermes, Inc., for the proposed indications of schizophrenia and bipolar I disorder.

10:00 a.m.	Call to Order	**Rajesh Narendran, MD** Chairperson, PDAC
10:15 a.m.	Introduction of Committee and Conflict of Interest Statement	**LaToya Bonner, PharmD** Acting Designated Federal Officer, PDAC
10:20 a.m.	FDA Opening Remarks	**Bernard Fischer, MD** Deputy Director (Acting) Division of Psychiatry (DP) Office of Neuroscience (ON) Office of New Drugs (OND), CDER, FDA
10:30 a.m.	**APPLICANT PRESENTATION**	**Alkermes, Inc.**
	Summary Presentation	**Sarah Akerman, MD** Senior Medical Director, Medical Affairs Alkermes, Inc.
11:00 a.m.	Clarifying Questions to Applicant	
11:30 a.m.	Clarifying Questions to FDA	
12:00 p.m.	**LUNCH**	
1:00 p.m.	**OPEN PUBLIC HEARING**	
2:00 p.m.	Questions to the Committee/Committee Discussion	
4:00 p.m.	**ADJOURNMENT**	