

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

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	