

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)*

October 9, 2020

QUESTIONS

1. **VOTE:** Has the Applicant presented adequate evidence that samidorphan meaningfully mitigates olanzapine-associated weight gain?
2. **VOTE:** Has the Applicant adequately characterized the safety profile of ALKS 3831 (olanzapine/samidorphan)?
3. **VOTE:** Is labeling sufficient to mitigate the risks related to the opioid antagonist action of samidorphan?
4. **DISCUSSION:** What, if any, additional data are needed to address outstanding issues of ALKS 3831 (olanzapine/samidorphan)?