

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

QUESTIONS

1. **VOTE:** Has substantial evidence been presented by the Applicant to support the effectiveness of buprenorphine/samidorphan for the adjunctive treatment of major depressive disorder?
2. **VOTE:** Has the Applicant adequately characterized the safety profile of buprenorphine/samidorphan for the adjunctive treatment of major depressive disorder?
3. **DISCUSSION:** Related to the potential risks associated with the use, misuse, and abuse of buprenorphine/samidorphan in post-market settings:
 - a) Discuss any concerns you have about the risks of misuse, abuse, addiction, or overdose with buprenorphine/samidorphan in the intended patient population or in others who may access the drug.
 - b) Discuss any concerns you have more generally about approving a product containing buprenorphine, an opioid, for the first time, for the treatment of depression.
 - c) Discuss whether you are concerned about the risk of opioid overdose if other opioids are used, misused, or abused concurrently with buprenorphine/samidorphan, perhaps in higher doses intended to overcome buprenorphine/samidorphan's μ -opioid antagonist effects, with potential additive opioid agonist effects that have not been fully characterized.
 - d) What risk reduction strategies could be implemented to decrease risks associated with buprenorphine/samidorphan use?
4. **VOTE:** Do the available data support a favorable benefit-risk profile of buprenorphine/samidorphan to support approval?
5. **DISCUSSION:** What, if any, additional data are needed pre- or post-approval to address outstanding issues with buprenorphine/samidorphan? Please be clear whether you believe these data should be required prior to approval.