

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) Meeting

FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
November 1, 2017

DRAFT QUESTIONS

1. **DISCUSSION:** Discuss whether the provided safety data sufficiently support the use of all of the proposed doses and formulations of CAM2038, given that the steady-state plasma exposures associated with some doses/formulations exceed those associated with the highest labeled dose of the reference product, Subutex? If not, describe which doses have adequate safety data.
2. **DISCUSSION:** Discuss whether the provided safety data sufficiently support the proposed indefinite use of both the weekly and monthly formulations.
3. **VOTE:** Do the provided safety data support:
 - a) all of the proposed doses
 - b) some of the proposed doses
 - c) none of the proposed doses
4. **VOTE:** Do the data from the clinical trial, taken together with the results of the blockade study, provide substantial evidence of effectiveness of CAM2038 weekly and monthly formulations for the treatment of opioid use disorder in patients who are newly initiating buprenorphine treatment for:
 - a) all of the proposed doses
 - b) some of the proposed doses
 - c) none of the proposed doses
5. **DISCUSSION:** Discuss the pros and cons of the restricted distribution under a Risk Evaluation and Mitigation Strategy (REMS) to mitigate the risks that might ensue from direct distribution of CAM2038 to patients.
 - a. What barriers to access may arise from implementing a restricted distribution system?
 - b. What systemic or institutional barriers might be anticipated for a restricted distribution system?
 - c. What modifications might address barriers to access while mitigating risk?
 - d. Is the proposed REMS sufficient, or are other measures needed?
6. **VOTE:** Do you recommend approval of this application for:
 - a) all of the proposed doses
 - b) some of the proposed doses
 - c) none of the proposed doses