

**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  
October 31, 2017

**QUESTIONS**

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1. **VOTE:** Do the data from the clinical trial, taken together with the results of the blockade study, provide substantial evidence of effectiveness of RBP-6000 for the treatment of opioid use disorder in patients who had undergone induction with a transmucosal buprenorphine product?
2. **VOTE:** Do the provided safety data sufficiently support the use of the proposed RBP 300 mg/300 mg dose regimen, given that the steady-state plasma exposures associated with RBP-6000 300 mg exceed those associated with the highest labeled dose of the reference product, Subutex?
3. **DISCUSSION:** Discuss the role of the RBP-6000 300/300 mg regimen, given the similarity in efficacy results between the RBP-6000 300/300 mg and RBP-6000 300/100 mg.
4. **DISCUSSION:** Discuss the pros and cons of the restricted distribution under a Risk Evaluation and Mitigation Strategy (REMS), as proposed by the Applicant, to mitigate the risks that might ensue from direct distribution of RBP-6000 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?
5. **VOTE:** Do you recommend approval of this application?