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

DRAFT 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?