FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Psychopharmacologic Drugs Advisory Committee (PDAC) Meeting
Tommy Douglas Conference Center
10000 New Hampshire Ave, Silver Spring, MD
March 27, 2018

DRAFT QUESTIONS

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1. **DISCUSSION:** Two concepts are under consideration, a) mitigation of symptoms associated with opioid withdrawal and b) facilitation of completion of abrupt opioid discontinuation treatment in patients with opioid use disorders (OUD).

   Discuss whether an effect on completion rates of abrupt discontinuation treatment is necessary to establish the clinical relevance of the efficacy data for mitigation of symptoms associated with opioid withdrawal. Could a finding of efficacy be made without data supporting both?

2. **VOTE:** Do the data provide substantial evidence of effectiveness of lofexidine for the mitigation of symptoms associated with opioid withdrawal?

3. **DISCUSSION:** Discuss the appropriateness of including facilitation of completion of abrupt opioid discontinuation treatment as a second indication. Is this supported by the data provided?

4. **DISCUSSION:** Discuss which dosing regimen is best supported by the data, given the similarity in efficacy results and differences in toxicity between the 3.2 mg and 2.4 mg per day doses.

5. **DISSCUSION:** Discuss the adequacy of the available safety data to support use between 7 and 14 consecutive days.

6. **VOTE:** Do you recommend approval of this application?

7. **DISCUSSION:** Discuss any issues that should be evaluated using postmarketing requirements.