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

Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) and the Drug Safety and Risk Management Advisory Committee (DSaRM)
College Park Marriott Hotel and Conference Center, General Vessey Ballroom
3501 University Blvd., Hyattsville, Maryland
May 22, 2018

DRAFT QUESTIONS

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1. **DISCUSSION:** Discuss whether based on the available data, the efficacy findings support the indication "management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate." In your discussion, include any concerns regarding the time to onset of analgesia for Buvaya in the context of an acute pain indication. Consider each dose of Buvaya in your discussion of time to onset of analgesia.

2. **DISCUSSION:** Based on the available safety data, discuss whether the safety profile of Buvaya is acceptable for the proposed indication.

3. **DISCUSSION:** Discuss any concerns you may have regarding the abuse or misuse of Buvaya and whether, based on the available data, the benefits to patients are expected to outweigh public health risks related to abuse and misuse.

4. **VOTE:** Overall, do the benefits of Buvaya outweigh the risks for the indication, "the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate," supporting approval of Buvaya?