

**FOOD AND DRUG ADMINISTRATION (FDA)**

Center for Drug Evaluation and Research (CDER)

***Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) Meeting***  
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)  
10903 New Hampshire Avenue, Silver Spring, Maryland  
October 11, 2018

**QUESTIONS**

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1. **DISCUSSION:** Discuss the efficacy of oliceridine and whether the data provide substantial evidence for efficacy of oliceridine for the proposed indication of the management of moderate-to-severe acute pain in adults for whom an intravenous opioid is warranted.
2. **DISCUSSION:** Discuss the safety profile of oliceridine and whether the safety profile of oliceridine is adequate to support approval of oliceridine for the proposed indication of the management of moderate-to-severe acute pain in adults for whom an intravenous opioid is warranted. Provide comment on the following issues:
  - a. Safety database
  - b. Hepatic safety
  - c. Respiratory safety
  - d. QT prolongation
3. **DISCUSSION:** Considering the abuse potential of oliceridine, and its proposed use for acute pain in adults for whom an intravenous opioid is warranted, please discuss any concerns you have regarding the impact of this product, if approved, on public health.
4. **VOTE:** Do you recommend approval of the proposed dose of oliceridine for the proposed indication of the management of moderate- to-severe acute pain in adults for whom an intravenous opioid is warranted. If not, what data are needed?