**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)***
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
June 7, 2016

**DRAFT QUESTIONS**

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1. **DISCUSSION:** Please discuss whether there are sufficient data to support a finding that Vantrela ER (hydrocodone bitartrate extended-release tablets) has properties that can be expected to deter abuse, commenting on support for abuse-deterrent effects for each of the three possible routes of abuse:

    a. Oral
    b. Nasal
    c. Intravenous

2. **VOTE:** Should Vantrela ER be approved for the proposed indication, management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate?

3. **VOTE:** If approved, should Vantrela ER be labeled as an abuse-deterrent product by the oral route of abuse?

4. **VOTE:** If approved, should Vantrela ER be labeled as an abuse-deterrent product by the nasal route of abuse?

5. **VOTE:** If approved, should Vantrela ER be labeled as an abuse-deterrent product by the intravenous route of abuse?