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 8, 2016

DRAFT QUESTIONS

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1. **DISCUSSION:** Please discuss whether there are sufficient data to support a finding that Troxyca ER (oxycodone hydrochloride and naltrexone hydrochloride extended-release capsules) 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 Troxyca 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 Troxyca ER be labeled as an abuse-deterrent product by the oral route of abuse?

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

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