

**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)***

Tommy Douglas Conference Center
10000 New Hampshire Avenue, Silver Spring, Maryland
April 5, 2017

DRAFT QUESTIONS

1. **DISCUSSION:** Please discuss whether there are sufficient data to support a finding that RoxyBond (oxycodone hydrochloride immediate-release tablets) has properties that can be expected to deter abuse, commenting on support for abuse-deterrent effects for each of the following routes of abuse:
 - a. Nasal
 - b. Intravenous
2. **VOTE:** If approved, should RoxyBond be labeled as an abuse-deterrent product by the nasal route of abuse?
3. **VOTE:** If approved, should RoxyBond be labeled as an abuse-deterrent product by the intravenous route of abuse?
4. **VOTE:** Should RoxyBond be approved for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate?