## **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

## **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?