

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
May 5, 2016

QUESTIONS

1. **DISCUSSION:** Please discuss whether the data presented for hydrocodone and acetaminophen combination drug products support that the nasal route of abuse is relevant for KP201/APAP.
2. **DISCUSSION:** Please discuss whether there are sufficient data to support a finding that KP201 has properties that can be expected to deter abuse commenting on support for deterrent effects for each of the three possible routes of abuse:
 - a. Oral
 - b. Nasal
 - c. Intravenous
3. **VOTE:** Should KP201/APAP be approved for the proposed indication?
4. **VOTE:** If approved, should KP201/APAP be labeled as an abuse-deterrent product?
5. **DISCUSSION:** If you think the product should be approved, discuss the route or routes of abuse for which abuse-deterrent language should be included in the product label.