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
November 14, 2018

QUESTIONS

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1. **DISCUSSION:** Please discuss whether there are sufficient data to support a finding that oxycodone hydrochloride immediate-release tablets (MNK-812) 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. **DISCUSSION:** The Applicant is requesting approval of oxycodone hydrochloride immediate-release tablets (MNK-812) as an analgesic with properties expected to deter abuse by the intravenous and intranasal routes. Discuss whether you have any concerns regarding the impact of this oxycodone hydrochloride immediate-release product (MNK-812) on public health. Take into consideration its potential effect on the abuse of opioids, including oxycodone, as well as potential consequences of administration of this product by unintended routes.

3. **VOTE:** If approved, should oxycodone hydrochloride immediate-release tablets (MNK-812) be labeled as an abuse-deterrent product by the nasal route of abuse?

4. **VOTE:** If approved, should oxycodone hydrochloride immediate-release tablets (MNK-812) be labeled as an abuse-deterrent product by the intravenous route of abuse?

5. **VOTE:** Should oxycodone hydrochloride immediate-release tablets (MNK-812) be approved for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate?