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)
DoubleTree by Hilton Hotel Bethesda – Washington DC, Grand Ballroom
8120 Wisconsin Avenue, Bethesda, Maryland
June 26, 2018

DRAFT QUESTIONS

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1. **DISCUSSION:** Please discuss whether the Applicant has demonstrated that Remoxy ER (oxycodone extended-release capsules) has properties that can be expected to deter abuse, commenting on each of the following routes of abuse:

    a. Oral
    b. Nasal
    c. Intravenous

2. **DISCUSSION:** Please discuss whether there are sufficient data to support inclusion of language regarding abuse-deterrent properties in the product label for Remoxy ER, commenting on support for abuse-deterrent effects for each of the following routes of abuse:

    a. Oral
    b. Nasal
    c. Intravenous

3. **DISCUSSION:** The Applicant is requesting approval of Remoxy ER 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 Remoxy ER on public health. Take into consideration its potential effect on abuse of extended-release oxycodone as well as potential consequences of administration of this product by unintended routes.

4. **VOTE:** Based on the data presented and the discussions about the data, do the efficacy, safety and risk-benefit profile of Remoxy ER support the approval of this application?