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
July 26, 2017

DRAFT QUESTIONS

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1. **DISCUSSION:** The Applicant submitted only Category 1 (in vitro) studies to support labeling of Oxycodone HCl ER tablets for abuse deterrence, and is seeking labeling for abuse-deterrent properties only for the IV route of abuse. The product contains excipients that are intended to deter abuse by other routes. Discuss whether it is appropriate to consider labeling this product for abuse-deterrent properties for a single route without a complete assessment of all relevant routes of abuse.

2. **DISCUSSION:** As presented earlier today, excipients in a drug product must have a purpose, and many oral formulations have excipients that pose health risks if injected. As discussed at previous advisory committee meetings, there have been concerns raised that the presence of excipients in abuse-deterrent formulations of products intended for oral use have resulted in additional toxicity to those who abuse these products by non-oral routes. This product contains a nasal irritant, SLS, and a blue dye, that, according to the Applicant, are intended to deter abuse by the nasal and oral routes, however, no data have been provided to support these claims.

    a. Discuss any concerns you may have regarding this product and the presence of excipients that have been included to deter abuse.

    b. Discuss whether it is acceptable to include excipients in this product that increase the potential risk from exposure via certain non-IV routes of abuse and have not been shown or are not intended to contribute to the proposed IV abuse-deterrent claim being sought by the Applicant.

    c. Discuss whether it is possible to determine an acceptable level of risk for excipients that may be toxic by unintended routes of administration for this product?

3. **DISCUSSION:** Although the Applicant is not currently seeking a nasal or oral abuse-deterrent claim, discuss the type of data that would be necessary to support a claim that blue dye has deterrent effects for the intravenous, nasal, or oral routes of abuse for this product. Discuss if it is acceptable to predict intranasal or oral abuse-deterrent effects from Category 1 studies alone for this product.

4. **VOTE:** Has the Applicant demonstrated that oxycodone extended-release tablets have properties that can be expected to deter abuse by the IV route of administration?

5. **VOTE:** Are there sufficient data for this product to support inclusion of language regarding abuse-deterrent properties in the product label for the IV route of administration?