FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Drug Safety and Risk Management Advisory Committee (DSaRM) and the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC)
Tommy Douglas Conference Center
10000 New Hampshire Avenue, Silver Spring, Maryland
March 13-14, 2017

DRAFT QUESTIONS

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1. **DISCUSSION:** Please discuss the strengths and limitations of the experimental and epidemiologic data regarding the safety concerns with reformulated Opana ER, including:

   a. The observed shift in abuse patterns from the nasal to injection route of abuse, and

   b. Reports of a TTP-like illness and HIV transmission associated with intravenous abuse of this drug

   How do the data inform our understanding of the risk/benefit balance for Opana ER, relative to other oxymorphone products?

2. **DISCUSSION:** Please discuss any potential consequences of taking regulatory action(s) relating to reformulated Opana ER, such as effects on prescribing or abuse patterns for other products, including other oxymorphone products.

3. **VOTE**: Do the benefits of reformulated Opana ER continue to outweigh its risks?