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

Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC), the Drug Safety and Risk Management Advisory Committee (DSaRM), and the Pediatric Advisory Committee (PAC)
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
September 15-16, 2016

DRAFT QUESTIONS

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1. **DISCUSSION:** Discuss safety concerns associated with the use and study of opioids in pediatric patients and whether patient selection or management of these risks should differ from adults. Include in the discussion the safety of opioid analgesics in pediatric patients in terms of adverse events, as well as risks of misuse, abuse, addiction, overdose, and death.

2. **DISCUSSION**: Clinical trials ideally enroll the target population for the study drug. Discuss the important factors that clinicians should incorporate into their decision to prescribe opioid analgesics in pediatric patients taking into consideration medical conditions, safety, and other factors you believe are important for proper patient selection.

3. **DISCUSSION:** Studies of immediate-release opioid analgesics are generally conducted in patients with acute painful conditions, including post-operative pain as well as traumatic or other painful conditions that require opioid analgesia and are expected to be of a relatively short duration.

   Studies of extended-release opioid analgesics are generally conducted in patients expected to require opioid treatment for at least 2 weeks who have pain severe enough to require an opioid, such as cancer pain, post-surgical pain for major procedures (i.e., major orthopedic surgeries), sickle-cell pain and others. Pediatric patients in studies of extended-release opioids are required to have received opioids for a period of time prior to entering the study to assure that they tolerate the lowest available strength of the ER opioid.

   Discuss incorporating the factors identified in Discussion #2 into the pediatric populations selected for the study of opioid analgesics.

4. **DISCUSSION:** As you have heard, extrapolation of efficacy from adults to pediatric patients down to 2 years of age is utilized in the development of opioid analgesics. We have had situations where the PK in pediatric patients was not similar to adults, as would have been expected. In this situation, would it be appropriate to identify a safe starting dose that would be titrated to effect, or should efficacy be evaluated?

5. **DISCUSSION:** You have heard about significant challenges associated with the study of opioid analgesics in pediatric patients. Discuss possible approaches to overcome these challenges.

6. **DISCUSSION:** Provide additional comments that you believe are important to address issues related to the use and study of opioid analgesics in pediatric patients.