FOOD AND DRUG ADMINISTRATION (FDA)
Office of the Commissioner (OC)

Joint Meeting of the Pediatric Advisory Committee (PAC) 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, MD
September 26, 2019

FINAL QUESTIONS

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1. **VOTE:** No new safety signals were identified for OxyContin (oxycodone hydrochloride) extended-release tablets in the current pediatric safety review. FDA recommends continuing ongoing, routine, post-market safety monitoring, along with completion of the post-marketing required studies by the sponsor. Does the Committee agree?

2. **DISCUSSION:** Pediatric patients have a need for adequate pain management that includes the use of opioids when appropriate. To accomplish this, product labeling should include appropriate pharmacokinetic, safety, and dosing information from clinical studies. Discuss appropriate strategies for describing the results of studies conducted under PREA in labeling taking into consideration the public health considerations of opioid misuse and abuse.

3. **DISCUSSION:** Extrapolation of efficacy from adults to pediatric populations down to two years of age and older for opioid analgesics has been acceptable provided that pharmacokinetic (PK) data demonstrate similar systemic exposure for adults and the pediatric population, and there are no additional safety concerns based on studies of pediatric patients with pain. However, situations arise in which the PK data demonstrate comparable exposures to the drug, but available efficacy data from the open-label safety study suggest dosing may not have been sufficient to provide adequate efficacy in the pediatric population as suggested in the study of Opana IR. Discuss whether information from the study in pediatric patients should be included in labeling, and if so, what information to include.

4. **DISCUSSION:** In the studies of Opana IR, notably higher systemic exposures were observed in 2 of the 24 patients in the PK and safety study conducted in 12 to 17 years of age (although one set of values suggests possible contamination of the sample). The patients did not experience any serious safety issues associated with these high levels. Discuss the implications a small number of patients with higher than expected drug levels when considering labeling an opioid analgesic with information from pediatric studies.

5. **VOTE:** Should pediatric labeling be approved for Opana IR (immediate-release oxymorphone)?

    a) If so, how should the pediatric information be described in labeling?