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

Joint Meeting of the 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
January 14, 2020

DRAFT QUESTIONS

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1. **DISCUSSION:** Clinical practice guidelines state that opioids should not be used as the initial therapy for patients with chronic low back pain and should only be used when patients have not responded adequately to non-opioid and non-pharmacologic therapies. Discuss whether the Applicant enrolled an appropriate patient population.

2. **DISCUSSION:** The Applicant conducted one pivotal efficacy study. Given that oxycodegol is a full mu-opioid receptor agonist, discuss if the data from the one efficacy study are substantial enough to support an indication in patients with chronic low back pain who have not responded adequately to non-opioid and non-pharmacologic therapies.

3. **DISCUSSION:** Based on the available safety data, discuss any concerns you may have about the safety profile of oxycodegol, including whether there is evidence for potential hepatic toxicity. Discuss any recommendations you have for patient management regarding the liver safety findings. Given that patients may use oxycodegol at doses higher than those for which adequate safety data are available, discuss whether any additional data are needed to further inform the safety profile of oxycodegol.

4. **DISCUSSION:** Considering the data that have been provided that address the abuse potential of oxycodegol, please discuss any concerns you have with the evaluation of its relative abuse liability and the potential impact of the abuse liability of this product on public health.

5. **VOTE:** Do you recommend approval of oxycodegol?
   A. YES, for the proposed indication of management of chronic low back pain in adult patients with pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.
   B. YES, for a general extended-release/long-acting opioid analgesic chronic pain indication.
   C. NO

   Please discuss the rationale of your vote. If you voted A or B, please specify whether any post-approval studies should be required. If you voted C, please discuss what additional data are needed.