

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 15, 2020 (**AM Session**)

DRAFT QUESTIONS

1. **DISCUSSION:** Considering the abuse potential of tramadol 44mg and celecoxib 56mg tablets, and its proposed use for the management of acute pain in adults that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate, please discuss any concerns you have regarding the impact of this product, if approved, on public health.
2. **DISCUSSION:** Discuss whether the benefits outweigh the risks for the proposed indication. Discuss if any additional data are needed for this application to be approved.
3. **VOTE:** Do you recommend approval of the proposed dose of tramadol 44mg and celecoxib 56mg tablets for the proposed indication of the management of acute pain in adults that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate?