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

Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) and the Drug Safety and Risk Management Advisory Committee (DSaRM)
November 2, 2020

DRAFT QUESTION

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1. **VOTE**: Based on the revised indication and proposed Risk Evaluation and Mitigation Strategy (REMS), which restricts the intended population and duration of use for Hydexor significantly from the originally submitted application, have the safety concerns been adequately addressed through labeling/REMS?

    a. If you voted "No," please comment on what additional issues the Applicant needs to address.