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 (**PM Session**)

QUESTIONS

1. **DISCUSSION:** Please discuss whether the Applicant has demonstrated that AXIMRIS XR (oxycodone extended-release tablets) has properties that can be expected to deter abuse by the following routes:

    1. Intravenous
    2. Intranasal
    3. Oral

2. **DISCUSSION:** The Applicant is requesting approval of AXIMRIS XR as an analgesic with properties expected to deter abuse by the intravenous route. Discuss the implications of approval of AXIMRIS XR that can be expected to deter abuse by a single route.

3. **DISCUSSION:** Discuss whether you have any concerns regarding the impact of AXIMRIS XR on public health. Take into consideration its potential effect on abuse of extended-release oxycodone as well as potential consequences of administration of this product by unintended routes.

4. **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.

5. **VOTE:** Do you recommend approval of AXIMRIS XR (oxycodone extended-release tablets) for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate?