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)
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
August 4, 2016

DRAFT QUESTIONS

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1. **DISCUSSION:** Please discuss whether there are sufficient data to support a finding that Arymo ER (morphine sulfate extended-release tablets) has properties that can be expected to deter abuse, commenting on support for abuse-deterrent effects for each of the three possible routes of abuse:

    a. Oral
    b. Nasal
    c. Intravenous

2. **VOTE:** If approved, should Arymo ER be labeled as an abuse-deterrent product by the oral route of abuse?

3. **VOTE:** If approved, should Arymo ER be labeled as an abuse-deterrent product by the nasal route of abuse?

4. **VOTE:** If approved, should Arymo ER be labeled as an abuse-deterrent product by the intravenous route of abuse?

5. **VOTE:** Should Arymo ER be approved for the proposed indication, management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate?