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

Joint Meeting of the Drug Safety and Risk Management Advisory Committee (DSaRM) and the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC)
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
June 11-12, 2019

QUESTIONS

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1. **DISCUSSION:** Discuss the role of higher daily doses and high dosage strength products of opioid analgesics in the management of pain.

   a. Discuss the settings or patient populations where there may be a clinical need for higher daily doses of opioid analgesics.

   b. Discuss the specific clinical utility of higher dosage strength opioid analgesic products, relative to lower dosage strength products.

2. **DISCUSSION:** Discuss the risks attributable to higher daily doses and higher dosage strength opioid analgesic products relative to lower daily doses and lower dosage strength products. In particular, discuss the differences in risks of misuse and abuse, addiction, and non-fatal or fatal overdose with high relative to lower daily doses or dose strengths.

   Include in your discussion the influence of therapy duration, physical opioid dependence, and other factors, as well as risks in different patient populations and to others who may access these drugs (e.g., young children, adolescents).

3. **DISCUSSION:** Discuss the potential impact on patient health and public health more broadly if FDA were to take any regulatory actions that resulted in reduced prescribing, access to, and use of higher dosage strength opioid analgesic products, specifically. Consider both positive and negative impacts on patients, healthcare delivery, and public health.

   a. What currently available evidence is most compelling in predicting the impacts of taking such actions?

   b. What are the most significant uncertainties (e.g., changes in prescribing behavior, rates of transition of patients to illicit drug use) in understanding the ultimate impact of such interventions on patients and public health?

   c. What additional evidence could help address these uncertainties?

4. **DISCUSSION:** Considering the discussion on all the previous questions, discuss whether there would be value in FDA taking any new regulatory actions intended to target or reduce prescribing and use of higher dosage strength opioid analgesic products.

   a. If FDA were to consider potential new regulatory actions, how might FDA define the products that would be subject to such actions?

   b. Discuss any other actions FDA should consider to improve the safety of higher dosage strength opioid analgesic products (i.e., actions not specifically intended to target or reduce prescribing and use).