

**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)***

September 10-11, 2020

**QUESTIONS**

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1. **DISCUSSION:** Discuss whether the evidence shows that OxyContin's reformulation with abuse-deterrent properties has meaningfully reduced its abuse (by one or more routes, or overall) and related adverse outcomes, including overdose. Please share the scientific rationale for your opinion, including what you believe to constitute a meaningful reduction.
  
2. **VOTE:** Does the available evidence demonstrate that the reformulation of OxyContin meaningfully reduced abuse of this product, relative to the original formulation, by one or more non-oral routes?
  - a. If you answer YES, please explain:
    - i. Which route(s) of abuse you believe have been meaningfully deterred by OxyContin's abuse-deterrent properties?
    - ii. In which population(s) you believe this effect has been demonstrated?
    - iii. How would you rate the strength of this evidence supporting your opinion, and which evidence did you find most compelling?
  
  - b. If you answer NO, please explain:
    - i. Whether you think the available data are sufficient to answer this question.
      1. If so, how would you rate the strength of this evidence supporting your opinion, and which evidence did you find most compelling?
      2. If not, what additional information do you think would be necessary to answer this question?
  
3. **VOTE:** Does the available evidence demonstrate that the reformulation of OxyContin meaningfully reduced overall abuse of this product, relative to the original formulation?
  - a. If you answer YES, please explain:
    - i. In which population(s) you believe this effect has been demonstrated?
    - ii. How would you rate the strength of this evidence supporting your opinion, and which evidence did you find most compelling?
  
  - b. If you answer NO, please explain:
    - i. Whether you think the available data are sufficient to answer this question.
      1. If so, how would you rate the strength of this evidence supporting your opinion, and which evidence did you find most compelling?
      2. If not, what additional information do you think would be necessary to answer this question?

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**QUESTIONS (cont.)**

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4. **VOTE:** Does the available evidence demonstrate that OxyContin's reformulation meaningfully reduced the risk of opioid overdose, relative to the original formulation?
- a. If you answer YES, please explain:
    - ii. In which population(s) you believe this effect has been demonstrated?
    - iii. How would you rate the strength of this evidence supporting your opinion, and which evidence did you find most compelling?
  - b. If you answer NO, please explain:
    - i. Whether you think the available data are sufficient to answer this question.
      - 1. If so, how would you rate the strength of this evidence supporting your opinion, and which evidence did you find most compelling?
      - 2. If not, what additional information do you think would be necessary to answer this question?
5. **DISCUSSION:** Discuss whether the available evidence indicates that the reformulation of OxyContin had any important unintended adverse consequences.
- a. If so, please explain what these unintended consequences were, in which population(s) you believe they occurred, and what evidence you found most compelling
  - b. If not, please explain whether you believe the available data are sufficient to answer this question, and if they were not, what additional information would be necessary to answer this question
6. **DISCUSSION:** Considering the totality of evidence, discuss the overall public health impact of the reformulation of OxyContin. Explain what evidence you found most compelling, and what additional information, if any, you think is needed to address this question.
7. **DISCUSSION:** Discuss what information, if any, you believe is important to convey to clinicians, patients, and the public about the postmarketing evidence of reformulated OxyContin's effectiveness in reducing abuse and related adverse outcomes, and/or its overall public health impact.