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
May 3-4, 2016

DRAFT QUESTIONS

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1. **DISCUSSION:** Considering the number of participants and completers in the Extended-Release (ER) and Long-Acting (LA) Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS) continuing education (CE) programs in the first 3 years of the program, please discuss:

    a. The expectations for the reach of an education program that is voluntary for prescribers, and whether the number of completers and participants is satisfactory.

    b. Whether the goal of training 80,000 prescribers of ER/LA opioid analgesics within 2 years was appropriate. If not, what is a reasonable expectation in light of the many competing programs?

2. **DISCUSSION: T**he effectiveness of the data sources and methodologies (e.g., surveys, surveillance, and drug utilization) used by the RPC to evaluate the impact of the ER/LA opioid analgesics REMS, particularly:

    a. The expectations for the reach of an education program that is voluntary for prescribers, and whether the number of completers and participants is satisfactory.

    b. Whether there are more effective short and long-term approaches to measure the success of the ER/LA Opioid Analgesics REMS in reducing serious outcomes resulting from inappropriate prescribing, misuse, and abuse of ER/LA opioid analgesics while maintaining patient access to pain medications.

    c. Whether the potential effects of the ER/LA Opioid Analgesics REMS on reducing abuse, misuse, addiction, overdose, and death can be differentiated from the many federal, state, local and health-system activities with similar goals.

    d. What is the anticipated length of time for an educational intervention to broadly impact prescriber knowledge and behaviors?

3. **DISCUSSION:** Please discuss the impact of the ER/LA Opioid Analgesics REMS on patient access to opioid analgesics; provide examples of how best to evaluate patient access.

4. **DISCUSSION:** Considering the information provided today regarding the current ER/LA Opioid Analgesics REMS, please discuss:

    a. Whether the REMS is meeting its stated goal to reduce serious adverse outcomes resulting from inappropriate prescribing, misuse, and abuse of extended-release or long-acting (ER/LA) opioid analgesics while maintaining patient access to pain medications.

b. Whether the REMS assures safe use of ER/LA opioid analgesics.

c. Whether the REMS is unduly burdensome on patient access to ER/LA opioid analgesics.

d. To the extent practicable, whether the REMS is minimizing burden on the healthcare delivery system.

5. **DISCUSSION:** Discuss whether the scope of the current FDA Blueprint is sufficient. If not, what should be added or deleted from the blueprint?

6. **DISCUSSION:** Discuss whether the current Medication Guide and Patient Counseling Document are sufficient. If not, what should be added or deleted?

7. **DISCUSSION**: Discuss whether a REMS for the immediate release (IR) opioid analgesics should be required to ensure their benefits outweigh their risks.

8. **DISCUSSION**: Discuss whether prescriber education should be required in order to prescribe an ER/LA or ER/LA and IR opioid analgesic. If so, considering any burden on the healthcare delivery system and patient access, discuss mandatory prescriber education via a restricted closed-system REMS or some other mechanisms by which education should be required (e.g., via DEA registration and renewal process, state licensing and renewal process).

9. **VOTE**: Considering all available information, which one of the following options do you recommend FDA pursue regarding the ER/LA Opioid Analgesics REMS?

   a. Continue without modifications
   b. Eliminate the REMS
   c. Modify the REMS

   After the vote**,** please describe the rationale for your recommended option. If you vote to modify the REMS, please discuss your rationale and provide specific recommendations for how it should be modified.

10. **DISCUSSION**: If any modifications are recommended, discuss how you would assess their impact on the safe use of ER/LA opioid analgesics; include how the impact of these modifications on patient access and healthcare delivery system burden could be assessed, if these differ from your responses to questions 2 and 3.