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

Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
October 12, 2018

QUESTIONS

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1. **DISCUSION:** Discuss whether the data are adequate to support a finding of efficacy for sufentanil sublingual tablets 30 mcg for the proposed indication: the management of moderate-to-severe acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate, in adult patients in a medically supervised setting.

2. **DISCUSSION**: Based on the available safety data, discuss any concerns you may have about the safety profile of sufentanil sublingual tablets 30 mcg.

3. **DISCUSSION:** Discuss whether data from the human factors studies and the clinical trials support the safe and effective use of the proposed product administered by healthcare professionals in certified settings such as hospitals, emergency departments, and surgical centers. In your discussion, consider whether the REMS proposed by FDA can be expected to mitigate the risks associated with dropped sufentanil tablets and including the risk of accidental exposure.

4. **DISCUSION**: Discuss any concerns you may have regarding the abuse or misuse of sufentanil sublingual tablets and whether, based on the available data, the benefits to patients are expected to outweigh public health risks related to abuse, misuse, and accidental exposure.

5. **VOTE:** Overall, do the benefits of sufentanil sublingual tablets 30 mcg with the REMS proposed by FDA outweigh the risks for the management of moderate-to-severe acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate, in adult patients in a medically supervised setting, supporting approval of sufentanil sublingual tablets 30 mcg?