

**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)***

Tommy Douglas Conference Center  
10000 New Hampshire Ave, Silver Spring, Maryland  
September 14, 2017

**QUESTIONS**

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1. **DISCUSSION:** Discuss any concerns you have regarding the data from the evaluation of Butrans in pediatric patients.
2. **DISCUSSION:** Discuss whether information from Study 3031 should be added to Section 8.4 Pediatric Use, in the Butrans label.
3. **DISCUSSION:** Discuss whether any additional labeling changes are supported by the data from Study 3031.