

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

DRAFT QUESTIONS

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.