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
February 14-15, 2018

DRAFT QUESTIONS

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1. **DISCUSSION:** What efficacy data are necessary to adequately evaluate the benefit of Exparel for nerve block?

   a. Discuss whether active comparator arms should be included in future efficacy studies of Exparel

   b. Discuss any circumstances where placebo-controlled studies alone are adequate to evaluate the efficacy of Exparel

2. **DISCUSSION:** The applicant has requested that Exparel be indicated "as a nerve block to produce regional analgesia."

   a. Discuss whether the efficacy data support the use of Exparel as a nerve block for the femoral nerve, intercostal nerves, or brachial plexus

   b. Discuss whether the data support any of the following:
      i. a broad indication for nerve block
      ii. individual nerve block indications
      iii. no nerve block indication

   c. If you do not find the data adequate to support any nerve block indication, describe the data that would be necessary to support this indication.

3. **DISCUSSION:** What safety data are necessary to adequately evaluate the risks of Exparel for nerve block?

   a. Discuss whether active comparator arms should be included in future studies of Exparel

   b. Discuss whether there are circumstances where placebo-controlled studies or open-label studies are adequate to assess the safety of Exparel

   c. Discuss whether the safety data submitted are adequate to characterize the safety profile of Exparel

4. **DISCUSSION:** Please discuss whether the data are adequate to support a change in the proposed indication from "administration into the surgical site to produce postsurgical analgesia" to "single-dose infiltration to produce local analgesia".

5. **DISCUSSION:** Please discuss any outstanding issues with this supplemental NDA that warrant additional studies, and if so, should these studies be conducted before or after approval.

6. **VOTE:** Do the efficacy, safety, and overall risk-benefit profile of Exparel support the approval of this supplemental application to add an indication for "nerve block to produce regional analgesia" or any individual nerve block indications?