DRAFT QUESTIONS

1. Has the applicant demonstrated the safety and effectiveness of fidaxomicin for the requested indication, treatment of *Clostridium difficile*-associated diarrhea (CDAD)? *(VOTE)*
   - If yes, are there any specific issues that should be addressed in labeling?
   - If no, what additional data are needed?

2. Is the finding of lower recurrence of CDAD at Day 31 in the fidaxomicin-treated subjects of clinical significance? *(VOTE)*
   - If yes, does it warrant discussion in product labeling?
   - If no, what additional data are needed?