

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

Gastrointestinal Drugs Advisory Committee (GIDAC) Meeting
Bethesda Marriott, Grand Ballroom
5151 Pooks Hill Road, Bethesda, Maryland
October 18, 2018

QUESTIONS

1. **VOTE:** Do the clinical trial data provide substantial evidence of effectiveness of prucalopride for the treatment of adults with chronic idiopathic constipation (CIC)? Discuss your answer.
2. **VOTE:** Has the potential risk of cardiovascular adverse events with the use of prucalopride in adults with CIC been adequately addressed by the Applicant? Discuss your answer.
 - a. **DISCUSSION:** If you answered NO to Question #2, what additional safety data do you recommend? Discuss your answer.
3. **VOTE:** Does the risk-benefit profile of prucalopride support the approval of this application? Discuss your answer.