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 17, 2018

QUESTIONS

1. **DISCUSSION:** Discuss the strength of the potential CV safety signal of tegaserod, considering the totality of available data from clinical trials, adjudications, pharmacoepidemiology studies, nonclinical data, and pharmacovigilance data.

2. **DISCUSSION:** Discuss other potential safety concerns, including psychiatric safety adverse events of completed suicide and suicidal ideation/behavior, when considering reintroduction of tegaserod to the U.S. market.

3. **VOTE:** Is the reintroduction of tegaserod to the U.S. market supported by the available safety data? Discuss your answer.

4. **VOTE:** Do you agree that the therapeutic gain (treatment difference between tegaserod and placebo patients) is generally similar in magnitude between the severely symptomatic and originally approved population? Discuss your answer.

5. **VOTE:** In which patient population would you expect the benefits to outweigh the risks for patients treated with tegaserod?
   A. IBS-C females
   B. IBS-C females at low CV risk
   C. IBS-C females who are severely symptomatic
   D. IBS-C females at low CV risk and who are severely symptomatic
   E. Other

   Discuss your answer.