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

Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting
September 21, 2023

DRAFT QUESTIONS

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1. **DISCUSSION:** Discuss your assessment of the safety profile of ITCA 650 and whether the safety profile of the ITCA 650 drug-device combination product has been adequately characterized based on available data:
    a. with respect to acute kidney injury
    b. with respect to cardiovascular safety
    c. with respect to overall safety

2. **DISCUSSION**: Discuss your assessment of the benefit risk balance of ITCA 650 for the indication to improve glycemic control in patients with type 2 diabetes mellitus (T2DM).

3. **VOTE:** Based on the available data has the Applicant demonstrated that the benefits of the ITCA 650 drug-device combination product outweigh its risks for the treatment of T2DM?
    a. If yes, explain your rationale.
    b. If no, explain your rationale and comment on additional data that could be provided to demonstrate the benefits outweigh the risks.