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

Medical Imaging Drugs Advisory Committee (MIDAC) Meeting
March 5, 2024

DRAFT QUESTIONS

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1. **DISCUSSION:** Discuss whether the observed performance of pegulicianine for patient-level detection of residual cancer, tissue-level sensitivity, and tissue-level specificity provide sufficient evidence of effectiveness.

2. **DISCUSSION**: Discuss the risk of serious hypersensitivity reactions associated with pegulicianine and the adequacy of risk mitigation and assessment strategies under consideration.

3. **VOTE:** Do the benefits of pegulicianine outweigh its risks?

    - If yes, describe the clinically meaningful benefit and the risk mitigation measures that are recommended.
    - If no, provide recommendations for additional data and/or analyses that may support a positive benefit/risk assessment of pegulicianine.