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

Medical Imaging Drugs Advisory Committee (MIDAC)
Augsust 1, 2023

DRAFT QUESTIONS

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1. **DISCUSSION:** Discuss the sufficiency of reviewed data from animal or human studies involving F 18, C 11, Ga 68, Cu 64, Rb 82, or N 13 to allow a reasonable calculation of radiation-absorbed dose to the whole body and critical organs upon first-in-human administration of a new PET drug containing one of these radionuclides.

2. **DISCUSSION:** Discuss the reasonableness of the approach under consideration involving administered activity values for new PET drugs containing F 18, C 11, Ga 68, Cu 64, Rb 82, and N 13, such that Phase 1 studies that will both (a) initially administer one or more activity levels ≤ value and (b) collect sufficient human data for dosimetry calculations may generally be found safe-to-proceed from a radiation safety perspective in the absence of dosimetry data based on prior animal administration of the new PET drug under investigation.