The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. The committee will discuss dosimetry data needed to support the initial clinical study in an original investigational new drug (IND) application for certain new positron emission tomography (PET) drugs. FDA would like to obtain the committee’s input on the following: (1) the sufficiency of available data from animal or human studies involving certain positron emitting radionuclides (e.g., C11, F18) to allow a reasonable calculation of radiation-absorbed dose to the whole body and critical organs upon administration of a new PET drug containing certain radionuclides to a human subject in first-in-human studies; and (2) the reasonableness of a proposed list of numerical radioactivity thresholds for new PET drugs containing these radionuclides, such that Phase 1 studies that will both (a) administer sub-threshold activities and (b) obtain sufficient human data for dosimetry calculations may be found safe-to-proceed in the absence of dosimetry data based on prior animal administration of the new PET drug under investigation.

12:00 p.m.  Call to Order  
Henry Royal, MD  
Chairperson, MIDAC

12:05 p.m.  Introduction of Committee and Conflict of Interest Statement  
Rhea Bhatt  
Designated Federal Officer, MIDAC

12:10 p.m.  FDA Introductory Comments  
Anthony Fotenos, MD, PhD  
Clinical Team Leader  
Division of Imaging and Radiation Medicine (DIRM)  
Office of Specialty Medicine (OSM)  
Office of New Drugs (OND)  
CDER, FDA

12:20 p.m.  **Guest Speaker Presentation**  
PET Dosimetry Preclinical and Human Experience for Clinical Research  
William Hallett, MD  
Head of Imaging Physics  
Invicro, LLC  
London

12:35 p.m.  **Speaker Presentation**  
Dosimetry for first-in-human PET studies  
The NIH experience  
Paolo Zanotti Fregonara, MD, PhD

12:50 pm  Clarifying Questions to Speakers
1:10 p.m. **FDA Presentations**

| Medical Physics Presentation | Donika Plyku, PhD  
Senior Staff Fellow  
DIRM, OSP, OND, CDER, FDA |
|-----------------------------|--------------------------------------------------|
| Nonclinical Perspective on  | Jonathan Cohen, PhD  
Biodistribution and Dosimetry Studies  
Supervisory Pharmacologist  
Division of Pharm/Tox, Office of Rare Diseases, Pediatrics, Urologic, and Reproductive Medicine (DPT-RDPURM)  
DIRM, OSP, OND, CDER, FDA |
| Pharmacovigilance Presentation | Samantha Cotter, PharmD  
Division of Pharmacovigilance (DPV) II  
Office of Pharmacovigilance and Epidemiology (OPE)  
Office of Surveillance and Epidemiology (OSE)  
CDER, FDA |

2:00 p.m. Clarifying Questions to Presenters

2:20 p.m. **BREAK**

3:00 p.m. **OPEN PUBLIC HEARING**

4:00 p.m. Questions to the Committee/Committee Discussion

5:00 p.m. **ADJOURNMENT**