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

Medical Imaging Drugs Advisory Committee (MIDAC) Meeting
August 1, 2023

DRAFT AGENDA

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	

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DRAFT AGENDA (cont.)

1:10 p.m.	**FDA PRESENTATIONS**	
	Medical Physics Presentation	**Donika Plyku, PhD** Senior Staff Fellow DIRM, OSP, OND, CDER, FDA
	Nonclinical Perspective on Biodistribution and Dosimetry Studies	**Jonathan Cohen, PhD** 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**	