

**FDA and Industry GDUFA III Implementation Quarterly Meetings – 4Qtr 2023 Meeting**  
**September 15, 2023, 9:00 AM – 11:00 AM**  
**Virtual Zoom Meeting**

**Agenda**

- Industry Inquiries on Implementation (Industry Led)
- PAIs (FDA Led)

**Participants**

<u>FDA:</u>		<u>Industry:</u>	
Tiana Barnes	CDER	Kiran Krishnan	AAM (Apotex)
Carter Beach	CDER	Scott Kuzner	AAM
Ashley Boam	CDER	Brian McCormick	AAM (Teva)
Jacqueline Corrigan-Curay	CDER	Giuseppe Randazzo	AAM
Alonza Cruse	ORA	Jeff Robinson	SKPharmTeco (BPTF)
Kristin Davis	CDER	Gil Roth	PBOA
Jill Furman	CDER	Molly Ventrelli	AAM (Fresenius Kabi)
Angela Granum	CDER	Brant Zell	BPTF (AmbioPharm)
Evelyn Hong	CDER		
Michael Kopcha	CDER		
Iilun Murphy	CDER		
Gisa Perez	CDER		
Mahesh Ramanadham	CDER		
Bethany Rue	CDER		
Ali Shariati	CDER		
Edward Sherwood	CDER		
Aaron Sigler	CDER		
Derek Smith	CDER		

**Industry Inquiries on Implementation**

Industry and FDA discussed several topics relating to current implementation activities.

**PAI's**

FDA provided clarification regarding timing for PAI requests and requirements to determine whether a PAI is needed.