

FDA and Industry GDUFA III Implementation Quarterly Meetings – 3Qtr 2023 Meeting
June 5, 2023, 1:00 PM – 3:00 PM
Virtual Zoom Meeting

Agenda

- Industry Inquiries on Implementation (Industry Led)
- Controlled Correspondence (FDA Led)

Participants

<u>FDA:</u>		<u>Industry:</u>	
Tiana Barnes	CDER	Deborah Attwood	BPTF (W.R. Grace)
Carter Beach	CDER	Joel Carpenter	BPTF
Ashley Boam	CDER	David Gaugh	AAM
Jacqueline Corrigan-Curay	CDER	Kiran Krishnan	AAM (Apotex)
Alonza Cruse	ORA	Brian McCormick	AAM (Teva)
Kristin Davis	CDER	Giuseppe Randazzo	AAM
Rebecca Frey-Cooper	CDER	Gil Roth	PBOA
Michael Kopcha	CDER	Brian McCormick	AAM (Teva)
Ilun Murphy	CDER	Molly Ventrelli	AAM (Fresenius Kabi)
Edward Sherwood	CDER	Brant Zell	BPTF (AmbioPharm)
Aaron Sigler	CDER		
David Skanchy	CDER		

Industry Inquiries on Implementation

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

Controlled Correspondence

FDA provided an update on the feedback provided by Industry at the February 2023 Quarterly Implementation Meeting.