

**FDA and Industry GDUFA III Implementation Quarterly Meetings – 1Q2023 Meeting
November 16, 2022 1:00 PM – 3:00 PM
Virtual Zoom Meeting**

Agenda

- Responses to Industry Inquiries on Implementation (Industry Led)
- Updates from FDA on Implementation Activities (FDA Led)

Participants

<u>FDA:</u>		<u>Industry:</u>	
Jacqueline Corrigan-Curay	CDER	Deborah Attwood	BPTF (W.R. Grace)
Tiana Barnes	CDER	John DiLoreto	BPTF
Carter Beach	CDER	David Gaugh	AAM
Ashley Boam	CDER	Kiran Krishnan	AAM (Apotex)
Alonza Cruse	ORA	Scott Kuzner	AAM
Kristin Davis	CDER	Brian McCormick	AAM (Teva)
Francis Godwin	CDER	Giuseppe Randazzo	AAM
Ilun Murphy	CDER	Gil Roth	PBOA
		Molly Ventrelli	AAM (Fresenius Kabi)

Responses to Industry Inquiries on Implementation

Industry asked questions related to the internal implementation activities associated with GDUFA III. FDA responded to these inquiries and provided updates as appropriate.

Updates from FDA on Implementation Activities

FDA provided updates on current implementation activities, including new IT changes necessary to implement the changes and took clarification questions from Industry on the Commitment Letter.