

FDA and Industry GDUFA III Implementation Quarterly Meetings – 2Qtr 2023 Meeting
February 6, 2023, 1:00 PM – 3:00 PM
Virtual Zoom Meeting

Agenda

- DMF Enhancements (FDA Led)
- Responses to Industry Inquiries on Implementation (Industry 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)
Kristin Davis	CDER	Scott Kuzner	AAM
Francis Godwin	CDER	Brian McCormick	AAM (Teva)
Michael Kopcha	CDER	Giuseppe Randazzo	AAM
Nancy Rolli	ORA	Gil Roth	PBOA
Susan Rosencrance	CDER	Cornell Stamoran	PBOA (Catalent)
David Skanchy	CDER	Andy Sweet	BPTF (Veranova)
		Molly Ventrelli	AAM (Fresenius Kabi)

DMF Enhancements

FDA provided status updates to Industry for the DMF Enhancements implemented in GDUFA III, highlighting that industry has not utilized the Prior Assessment for DMFs to the extent predicted.

Responses to Industry Inquiries on Implementation

FDA provided updates on current implementation activities.