

FDA and Industry OMuFA Implementation Meeting
August 29, 2023

Agenda:

- **FDA Updates**
- **Industry Updates and Discussion Topics**

Participants:

FDA		Industry	
Carol Bennett	CDER (ORP)	Lisa Parks	CHPA
Theresa Michele	CDER (OND)	David Spangler	CHPA
Karen Murry	CDER (OND)	Jay Sirois	CHPA
Elisabeth Walther	CDER (OND)	Lauren Quinn	CHPA (Haleon)
Celia Peacock	CDER (OND)	James Kim	CHPA (ACI)
Michael Boblitz	CDER (OND)		
Andrea Frydl	CDER (OCOMM)		
Angela Granum	CDER (OM)		
Matthew Brancazio	CDER (OM)		
Grace Carmouze-Cunningham	CDER (OEP)		

FDA Updates:

FDA indicated the following changes due to occur on October 1, 2023:

- The Annual Forecast for Planned Monograph Activities is due to be posted.
- Certain over-the-counter monograph order request (OMOR) performance goals will begin, and monograph meeting management performance goals increase.
- CDER NexGen Portal is scheduled to go live to accept OMOR submissions.

FDA reviewed the timeline for publication of final guidance documents.

FDA noted that an OMuFA II public meeting is scheduled for September 28, 2023, in the FDA White Oak Building 31, Great Room, and will also be available via webcast.

FDA provided an update on user fee collections for fiscal year (FY) 2023.

FDA provided updates on hiring and communications.

Industry Updates and Discussion Topics:

FDA and Industry discussed the following:

- OMuFA II Process and Protocol for the Negotiation Meeting.
- Industry expectations for OMOR submissions in FY 2024.
- Questions received by industry regarding OTC Monographs @ FDA Portal content.