

**FDA and Industry OMFUFA Progress Meeting
September 1, 2022**

Agenda:

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

Participants:

FDA		Industry	
Carol Bennett	CDER (ORP)	Barbara Kochanowski	CHPA
Anuj Shah	CDER (ORP)	David Spangler	CHPA
Theresa Michele	CDER (OND)	Lauren Quinn	CHPA (Haleon)
Karen Murry	CDER (OND)	James Kim	CHPA (ACI)
Dan Brum	CDER (OND)		
Michael Boblitz	CDER (OND)		
Grace Carmouze-Cunningham	CDER (OEP)		
Kimberly Rawlings	CDER (OCOMM)		
Matthew Brancazio	CDER (DUFM)		

FDA Updates:

FDA stated that monograph meeting management performance goals begin October 1, 2022.

FDA reviewed the timeline for publication of guidance documents.

FDA stated that a Federal Register notice was posted on March 16, 2022, announcing the FY 2022 OMFUFA fee rates. FDA noted that fees were due on June 1, 2022, and an arrears list is published monthly.

FDA indicated that the Annual Forecast for Planned Monograph Activities is due to be posted on October 1, 2022.

FDA noted that Deemed Final Orders continue to be published on a rolling basis.

FDA provided updates on IT developments, cataloging paper documents, and hiring.

Industry Updates and Discussion Topics

FDA and Industry discussed the following:

- Format and duration of monograph meetings.
- Safety labeling changes under the administrative order process.
- Scheduling of OMFUFA Progress Meetings for 2022 and 2023.