FDA and Industry OMUFA Progress Meeting
December 1, 2022

Agenda:

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

Participants:

FDA		Industry	
Carol Bennett	CDER (ORP)	Barbara Kochanowski	CHPA
Theresa Michele	CDER (OND)	David Spangler	CHPA
Karen Murry	CDER (OND)	Lauren Quinn	CHPA (Haleon)
Celia Peacock	CDER (OND)	James Kim	CHPA (ACI)
Michael Boblitz	CDER (OND)		
Kristen Booze	CDER (OCOMM)		
Teresa Ramson	CDER (DUFM)		

FDA Updates:

The annual forecast of planned monograph activities posted on September 30, 2022.

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

FDA reviewed the timeline for publication of draft and final guidance documents.

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

FDA provided updates on User Fee:

- FDA continues to collect fees from OTC facilities. We have not yet collected the full target revenue of $23.888 M. However, we are making great progress in meeting that goal. The final FY 2022 collections will be provided in the annual financial report.
- The arrears list, which is publicly available, shows that there are 612 facilities on arrears for FY 2022 (compared to 394 facilities for FY 2021). Of the 612 facilities on the FY 2022 arrears list, 253 facilities were also on the FY 2021 arrears list.

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

Industry Updates and Discussion Topics:

FDA and Industry discussed the following:

- Plans for future discussions on OMUFA II

- Industry provided feedback on the CDER NextGen Portal
- Notification process for announcement of proposed orders and calls for data
- Scheduling of OMUFA Progress Meetings for 2023