FDA and Industry OMUFA Progress Meeting
April 19, 2022

Agenda:

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

Participants:

FDA		Industry	
Carol Bennett	CDER (ORP)	Barbara Kochanowski	CHPA
Michael Bernstein	CDER (ORP)	David Spangler	CHPA
Theresa Michele	CDER (OND)	Lauren Quinn	CHPA (GSK)
Karen Murry	CDER (OND)	James Kim	CHPA (ACI)
Celia Peacock	CDER (OND)		
Sherry Stewart	CDER (OND)		
Michael Boblitz	CDER (OND)		
Grace Carmouze-Cunningham	CDER (OEP)		
Kristen Booze	CDER (OCOMM)		
Kimberly Rawlings	CDER (OCOMM)		
Teresa Ramson	CDER (DUFM)		

FDA Updates:

FDA stated that the draft guidance "Formal Meetings Between FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs" was posted on February 1, 2022. Subsequently, a webinar on the draft guidance was held on March 29, 2022, for which a recording is available.

FDA stated that a Federal Register notice was posted on March 16, 2022, announcing the FY 2022 OMUFA fee rates, with fees being due on June 1, 2022.

FDA noted that Deemed Final Orders for ophthalmic products and antidiarrheal products posted on April 4, 2022.

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

Industry Updates and Discussion Topics

Industry provided feedback to FDA on structure and content of the OMUFA and OTC Monograph Reform website.

FDA and Industry discussed monograph meeting requests, including prioritization, granting, and scheduling of meetings. FDA noted that meeting management performance goals will take effect beginning October 1, 2022.

Industry and FDA reviewed the schedule of OMUFA Progress meetings planned for 2022.