FDA and Industry OMUFA Progress Meeting
August 31, 2021

Agenda:

- **FDA updates**
- **Industry updates**
- **Discussion topics**

Participants:

FDA		Industry	
Carol Bennett	CDER (ORP)	Barbara Kochanowski	CHPA
Theresa Michele	CDER (OND)	David Spangler	CHPA
Karen Mahoney	CDER (OND)	Valerie Gallagher	CHPA (Perrigo)
Celia Peacock	CDER (OND)	James Kim	CHPA (ACI)
Mary Vienna	CDER (OEP)		
Teresa Ramson	CDER (OM)		
Kristen Booze	CDER (OCOMM)		
Michael Boblitz	CDER (OND)		

FDA updates:

FDA noted that the goal date to publish the annual forecast is October 1, 2021.

FDA reported that it continues to collect fees from OTC facilities. Invoices to those facilities that had not satisfied their OMUFA user fees were emailed on June 25, 2021 – this information was posted to the OMUFA website (https://www.fda.gov/industry/fda-user-fee-programs/over-counter-monograph-user-fee-program-omufa). Final FY 2021 collections will be provided in the annual financial report.

The date to publish the FY 2022 Federal Register notice to set the FY 2022 fee rates has not yet been determined.

The facility fee due date for Fiscal Year 2022 is June 1, 2022.

FDA led a discussion on the progress of posting the Deemed Final Orders (DFOs), DFO format, and removal of content from the Code of Federal Regulations (CFR).

FDA updated industry on the interim IT system, OTC Monographs@FDA, which will serve as a repository of monograph orders.

FDA and Industry discussed the following:

- Meeting requests
- Documents for public release

- Clarification regarding confidentiality
- Current resources

Industry updates:

Industry reported that meeting requests have been actively prepared and submitted and expressed willingness to work with FDA on the content and format of the requests. FDA reported it continues to work on providing documents for public release, clarification regarding confidentiality and meeting timelines. Further updates are forthcoming at future meetings.