

**FDA and Industry OMFUFA Progress Meeting
December 13, 2021**

Agenda:

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

Participants:

FDA		Industry	
Michael Bernstein	CDER (ORP)	Barbara Kochanowski	CHPA
Theresa Michele	CDER (OND)	David Spangler	CHPA
Karen Murry	CDER (OND)	Valerie Gallagher	CHPA (Perrigo)
Celia Peacock	CDER (OND)	James Kim	CHPA (ACI)
Sherry Stewart	CDER (OND)		
Michael Boblitz	CDER (OND)		
Grace Carmouze-Cunningham	CDER (OEP)		
Matthew Brancazio	CDER (OM)		

FDA updates:

FDA stated that recordings of Small Business and Industry Assistance (SBIA) webinars have been and will continue to be posted for viewing.

FDA noted that the annual forecast was published on October 1, 2021 with a goal of publishing the next forecast by October 1, 2022. FDA said that the items in the forecast are a rolling list of planned monograph activities that FDA intends to address over the ensuing 3 years and are not listed in any particular order.

FDA plans to publish the Federal Register notice announcing the FY 2022 OMFUFA fee rates in early 2022, with fees being due on June 1, 2022.

FDA provided an update on the sunscreen proposed order and the progress of posting the Deemed Final Orders (DFOs) to OTC Monographs@FDA.

FDA reported that it has begun to receive meeting requests from industry.

FDA provided an update on current resources and hiring.

Industry updates:

Industry reported that its members have increased production of alcohol-based hand sanitizers to meet current demands.

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