

**FDA and Industry OMUFA Implementation Meeting
December 2, 2024**

Agenda:

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

Participants:

FDA		Industry	
Carol Bennett	CDER (ORP)	Michael Bailey	CHPA
Michael Bernstein	CDER (ORP)	David Spangler	CHPA
Anuj Shah	CDER (ORP)	James Kim	ACI
Theresa Michele	CDER (OND)	Gil Roth	PBOA
Karen Murry	CDER (OND)	Cornell Stamoran	Catalent
Celia Peacock	CDER (OND)	Erin Oliver	Haleon
Michael Boblitz	CDER (OND)	Michael Kaminski	P&G
Andrea Frydl	CDER (OCOMM)	Mary Schilling	PCPC
Angela Granum	CDER (OM)		
Kimberly Taylor	CDER (OSP)		
Genevieve Huss	CDER (OEP)		

FDA Updates:

FDA noted that it is continuing to meet and exceed goals with respect to monograph meeting requests.

FDA reviewed the status of recent proposed administrative orders.

FDA reviewed the status of remaining OMUFA I guidances.

FDA noted that the November 20, 2024, OMUFA II Public Meeting went well in its opinion.

FDA provided a hiring update.

FDA provided an update on communications, including recent consumer updates related to antibacterial soap and cold medicine for children, the fourth monograph forecast, a From Our Perspective article, and proposed order outreach.

Industry Updates

Industry noted that the template used for the phenylephrine proposed order was effective in communicating necessary information about the order.

Discussion Topics:

FDA and Industry discussed the following:

- Monographs without a Deemed Final Order (e.g., Overindulgence)
- Arrears List
- Annual Forecast Terminology