

**FDA and Industry OMUFA Implementation Meeting
August 5, 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)	Gil Roth	PBOA
Theresa Michele	CDER (OND)	Mark Gardella	PBOA
Karen Murry	CDER (OND)	Cornell Stamoran	Catalent
Celia Peacock	CDER (OND)	Erin Oliver	Haleon
Michael Boblitz	CDER (OND)	James Kim	ACI
Andrea Frydl	CDER (OCOMM)	Wendy McManus	Sanofi
Angela Granum	CDER (OM)		
Kimberly Taylor	CDER (OSP)		

FDA Updates:

FDA noted the first FDA-initiated proposed order was posted on June 14, 2024, to OTC Monographs @ FDA, but that due to technical difficulties, the comment period would be reopened with a later deadline.

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

FDA noted the fiscal year 2025 Federal Register notice (FRN) establishing over-the-counter monograph order request (OMOR) fee rates was published on July 31, 2024.

FDA provided updates on hiring.

FDA provided an update on communications including recent consumer and website updates related to nonprescription drugs as well as the status of our consumer social media outreach related to sunscreens.

Industry Updates and Discussion Topics:

FDA and Industry discussed the following:

- Strategies for submitting meeting requests and obtaining feedback.
- Public posting of monograph meeting materials.
- Industry feedback regarding the arrears list.