Over-The-Counter Monograph Drug User Fee Program (OMUFA) Reauthorization

FDA and Industry Negotiations | Meeting Summary

December 5, 2023 | 9:30am-3:30pm

In-Person Format

PURPOSE

To review reframed Industry proposals, review industry's feedback on the scope of FDA's proposals, and present industry's information technology (IT) proposals.

PARTICIPANTS

FDA		**Industry**	
Ashley Boam	CDER	James Kim	ACI
Joshua Brown	OC	Katie Kramer	ACI (Hogan Lovells)
Grace Carmouze-Cunningham	CDER	Michael Kaminski	CHPA (P&G)
Christine Hunt	OC	Wendy McManus	CHPA (Sanofi)
Bharat Khanna	CDER	Lauren Quinn	CHPA (Haleon)
Theresa Michele	CDER	Lisa Parks	CHPA
Karen Murry	CDER	David Spangler	CHPA
Celia Peacock	CDER	Gil Roth	PBOA
Phong Pham	CDER	Mary Schilling	PCPC
Paul Phillips	CDER		
Kimberly Taylor	CDER		

Industry's Reframed Proposals

Industry presented proposals they had reframed given FDA's feedback that they appeared out of scope for OMUFA II negotiations, and FDA asked clarifying questions. Due to remaining issues, this topic will be revisited at the next negotiation meeting.

Industry Feedback on Scope of FDA proposals
Industry presented their feedback on scope for FDA's proposals and asked clarifying questions. This topic will be revisited at the next negotiation meeting.

Industry IT Proposals
Industry presented several proposals related to desired updates to FDA's website to capture historical information about OTC monographs, exclusivity information, and General Recognized As Safe and Effective (GRAS/E) status.

Next Steps
At the next meeting, FDA and Industry proposals identified as outside the authorized scope will be revisited. The fuller agenda for the next meeting will be determined by the negotiation leads at their planning meeting.