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

FDA and Industry Negotiations | Meeting Summary

December 19, 2023 | 9:30am-2:20pm

Virtual Format (Zoom)

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)
Angela Granum	CDER	Wendy McManus	CHPA (Sanofi)
Christine Hunt	OC	Lisa Parks	CHPA
Bharat Khanna	CDER	David Spangler	CHPA
Theresa Michele	CDER	Mary Schilling	PCPC
Karen Murry	CDER		
Celia Peacock	CDER		
Phong Pham	CDER		
Paul Phillips	CDER		
Kimberly Taylor	CDER		

FDA Financial Proposals
FDA addressed Industry's follow-up questions on FDA's proposals regarding the facility fee due date change and baseline target revenue. Industry requested information on the timeframe for user fee invoicing and on OMUFA I Information Technology spending needs. FDA agreed to provide follow-up information.

Public Comment Period and Extension of Goal Date for Final Orders
FDA responded to follow-up questions from Industry. It was noted that FDA's proposal intends to provide transparency to the process for all stakeholders.

New Meeting Type Proposal
Industry presented follow-up information to support their proposal for a new meeting type "W" (analogous to "Type D" under the PDUFA VII commitment letter). FDA asked clarifying questions and requested additional information to help determine potential impact on workload. Industry agreed to provide this information.

Industry IT Proposals

Industry presented FDA-requested information in support of Industry's IT proposals (updates to FDA's website to capture historical information about OTC monographs; information about monograph orders that are associated with exclusivity; and data regarding active ingredients that are not subject to a final FDA Generally Recognized As Safe and Effective (non-GRAS/E)) determination. FDA asked clarifying questions and requested additional information on the non-GRAS/E active ingredients IT proposal. Industry agreed to provide this information at a future meeting. In addition, FDA will discuss with internal subject matter experts the feasibility of modifying the historical information webpage and posting order exclusivity information on FDA's website.

Next Steps
The agenda for January 9th will be determined by the negotiation leads at their next planning meeting.