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

FDA and Industry Negotiations | Meeting Summary

February 20, 2024 | 9:30am-11:10am

Virtual Format (Zoom)

PARTICIPANTS

FDA	Office	Industry	Organization
Ashley Boam	CDER	James Kim	ACI
Joshua Brown	OC	Katie Kramer	ACI (Hogan Lovells)
Grace Carmouze-Cunningham	CDER	Barbara Kochanowski	CHPA
Angela Granum	CDER	Michael Kaminski	CHPA (P&G)
Christine Hunt	OC	Wendy McManus	CHPA (Sanofi)
Bharat Khanna	CDER	Erin Oliver	CHPA (Haleon)
Theresa Michele	CDER	David Spangler	CHPA
Karen Murry	CDER	Mark Gardella	PBOA
Celia Peacock	CDER	Mary Schilling	PCPC
Phong Pham	CDER		
Paul Phillips	CDER		
Kimberly Taylor	CDER		

OMUFA Facility Fee Due Date Change Proposal

FDA presented its response to Industry's feedback on transitioning to the proposed new facility fee due date (October 1st). Based on Industry feedback, FDA proposed a modified installment plan for fiscal year (FY) 2027 facility fee payments. In addition, FDA presented an overview of the OMUFA inflation calculation. In order to transition to a new facility fee liability period under OMUFA II, FDA also provided options and tradeoffs for Industry consideration. FDA addressed Industry's clarifying questions. This proposal will be discussed further at a subsequent meeting.

Monograph Testing Procedures Proposals

In follow-up to Industry's information request related to its two monograph testing procedure proposals (i.e., (1) recharacterization and changes to monograph testing procedures and (2) amending the statutory definition of a Tier 2 OMOR to include OMORs proposing certain changes in monograph testing procedures), FDA provided information on Deemed Final Orders (DFOs) with test methods. In addition, FDA addressed Industry's initial questions and referred Industry to the

2023 guidance document entitled CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality as a reference on certain FDA standards recognition. For the recharacterization and changes to testing procedures proposal, Industry will review the information and, based on this information, provide FDA with a proposed number of workshops and related OMORs. This proposal will be discussed further at a subsequent meeting.

Guidance Documents Proposals

Industry presented four proposals for FDA guidance documents. Three of the guidance topics were: WRO vs. live meetings, content outline for Tier 2 OMORs, and confidential information. In addition, Industry proposed FDA consider issuing a proposed administrative order for minor changes for dosage forms other than solid oral along with a guidance providing the details on how to comply with this proposed administrative order. Industry addressed FDA's initial questions. For the confidentiality guidance proposal, FDA requested more clarity on the examples provided and additional information regarding what Industry would want FDA to consider covering as part of this guidance. This proposal will be discussed further at a subsequent meeting.

Next Steps

The final agenda for the February 27th meeting will be determined by the negotiation leads at their next planning meeting.