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

FDA and Industry Negotiations | Meeting Summary

February 27, 2024 | 9:30am-11:55am

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	Lynn Evans	CHPA (Kenvue)
Angela Granum	CDER	Barbara Kochanowski	CHPA
Christine Hunt	OC	Michael Kaminski	CHPA (P&G)
Jennifer Maguire	CDER	Wendy McManus	CHPA (Sanofi)
Theresa Michele	CDER	Erin Oliver	CHPA (Haleon)
Karen Murry	CDER	David Spangler	CHPA
Celia Peacock	CDER	Cornell Stamoran	PBOA
Phong Pham	CDER		
Paul Phillips	CDER		
Kimberly Taylor	CDER		

OMUFA Facility Fee Due Date Change Proposal
Industry indicated its support for FDA's modified installment proposal for fiscal year (FY) 2027 facility fee payments. In addition, in response to FDA's proposed options for the liability period for the annual facility fees during the OMUFA II transition, Industry provided its preference. Industry indicated there are no further questions for this proposal.

OMUFA Facility Fee Adjuster Proposal
Industry provided feedback on FDA's facility fee adjuster proposal. FDA agreed to provide any publicly available information on supplemental funding used for OTC monograph drug activities during the coronavirus disease 2019 (COVID-19) pandemic after OMUFA I took effect. Industry will follow up on any projection information regarding hand sanitizer manufacturers potentially staying in the market. This proposal will be discussed further at a subsequent meeting.

Major Amendments Clarification Proposal
Industry indicated they supported this proposal and had no further questions.

CDER Manual of Policies and Procedures (MAPPs) Proposals
In response to FDA's request, Industry presented its priorities for their five proposed FDA MAPPs, with a MAPP addressing FDA-initiated GRASE orders being the highest. Industry also indicated that they wanted MAPPs to include detailed content and format information for an OMOR. FDA reiterated that discussions regarding substantive details on the information contained in MAPPs and guidances are out of scope of these user fee reauthorization negotiations. In addition, FDA reminded Industry that MAPPs are intended for FDA staff use. Industry noted that publicly-available MAPPs are helpful to Industry. This proposal will be discussed further at a subsequent meeting.

Industry Cataloguing Paper Document (Scanning and Posting Documents) Proposals
In response to FDA's counterproposal for enhancements to the paper document cataloguing project in OMUFA II, Industry indicated they support the work outlined. Resource discussions for this proposal will continue. This proposal will be discussed further at a subsequent meeting.

Quality Proposals
Industry presented feedback on FDA's three product quality-related proposals. Industry acknowledged FDA's desire to increase efforts to ensure quality medicines to the public and voiced a desire to focus the proposals on high-risk areas. Given the need to address this important topic, both FDA and Industry agreed to continue discussion on quality. This topic will be discussed further at a subsequent meeting.

Monograph Testing Procedures Proposals
Industry presented questions to FDA on Industry's two monograph testing procedure proposals (i.e., (1) recharacterization and changes to monograph testing procedures and (2) amending statutory definition of Tier 2 OMOR to include OMORs proposing certain changes in monograph testing procedures). Industry indicated its support of FDA's proposed legislative language for the revised definition of Tier 2 OMOR. Industry agreed to provide additional information on OMUFA II OMOR estimates for the purpose of resourcing. These proposals will be discussed further at a subsequent meeting.

Filing Eligibility Determinations Guidance Proposal
FDA presented follow-up on scope and timeline goals for a potential guidance document on filing eligibility determinations for OMORs proposing new monograph drug active ingredients. FDA agreed to return with resourcing estimates and Industry agreed to consider the proposed timelines. This proposal will be discussed at a future meeting.

Next Steps
The final agenda for the March 5th meeting will be determined by the negotiation leads at their next planning meeting.