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

FDA and Industry Negotiations | Meeting Summary

March 12, 2024 | 9:30am-12:20pm

In-Person Format

PARTICIPANTS

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

Overview of OMUFA-Funded Full-Time Equivalents
In an effort to provide better understanding on full-time equivalent (FTE) data provided in response to Industry's information request, FDA presented information on the OMUFA I hiring process, how FTEs are measured, how Budget Authority (BA) funds support the program, contributions to the program from FDA staff outside of CDER, and how FDA manages OMUFA-funded FTEs. FDA addressed Industry's clarifying questions. FDA agreed to provide additional information on BA spending for user fee-allowable activities. This topic will be discussed further at a subsequent meeting.

OMOR and Meetings Estimates for OMUFA II
Industry presented requested information on their estimates for expected future numbers of OMOR submissions and meeting requests. Industry provided information on how these estimates were determined and addressed FDA's clarifying questions.

CDER Manual of Policies and Procedures (MAPPs) and Guidance Proposals
In response to Industry's five MAPP and five guidance proposals, FDA presented its

counterproposal to issue a subset of the requested guidances and MAPPs that cover topics of use to both Industry and FDA. Guidance topics proposed included confidentiality (expanding on the discussion of confidentiality in existing draft guidance on OMOR format and content) and filing eligibility for OMORs proposing new monograph drug active ingredients. MAPP topics proposed included the processes and procedures for safety orders and expedited safety orders. FDA addressed Industry's initial clarifying questions. FDA agreed to consider Industry's suggestions to create mechanisms for engagement with Industry in advance of FDA issuing a guidance.

For the guidance on the confidential information proposal, Industry presented its response to FDA's request for more information. Industry provided additional context for this request and hypothetical situations where there are questions of whether information could/could not be disclosed. Industry addressed FDA's clarifying questions.

These proposals will be discussed further at a subsequent meeting.

Meetings Proposals
Industry presented its initial feedback to FDA's meetings counterproposals. For Type X and Y meetings and face-to-face meetings for complex scientific or regulatory issues, Industry indicated support for FDA's proposal to include language in the Commitment Letter regarding FDA taking into consideration the complexity of the meeting topics when determining whether a WRO vs a live interaction is granted, and when determining the meeting length (i.e., extending beyond the standard one-hour meeting timeframe). FDA emphasized if the meeting briefing package is sufficiently complete, then Industry can use the time more efficiently by eliminating lengthy presentations and thus allowing more time to address complex issues. FDA agreed to consider Industry's request to track OMUFA II meeting metrics for future data calls.

In addition, Industry indicated support for FDA to establish an OMUFA "follow-up opportunity" mechanism similar to the mechanism under the PDUFA VII commitment letter. FDA agreed to consider Industry's request to link requested FDA clarification of minutes to the meeting date.

These proposals will be discussed further at a subsequent meeting.

Advisory Committee Meeting Proposal
Industry also provided initial feedback on the FDA's Advisory Committee Meetings (AdComs) counterproposal. Industry reiterated its interest in advanced notification and offered suggestions regarding how that could be accomplished, such as by announcing anticipated monograph-related AdComs in the OMUFA annual forecast. FDA reminded Industry that FDA's 2008 Guidance on Advisory Committee Meetings; Preparation and Public Availability and applicable FDA regulations outline well-established agency-wide practices on when and how AdComs are announced. This proposal will be discussed further at a subsequent meeting.

Monograph Testing Procedures Proposals
Industry indicated it had no further questions for the NextGen Portal capabilities regarding differentiating Tier 1 and Tier 2 submissions. Industry suggested that training on how to use the Portal may be helpful. Based on the estimates for OMOR submissions in OMUFA II provided by Industry, FDA will begin developing resource estimates for these proposals. These proposals will be discussed further at a subsequent meeting.

IT Platform – Information on Proposed FDA Website Regarding Final Orders Providing Exclusivity Proposal

Industry indicated support for FDA's counterproposal to acknowledge exclusivity for a final order on FDA's website. Industry will propose draft language to 1) acknowledge exclusivity in a proposed order and 2) accompany the webpage posting. This proposal will be discussed further at a subsequent meeting.

Next Steps

The final agenda for the March 25th meeting will be determined by the negotiation leads at their next planning meeting.