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

FDA and Industry Negotiations | Meeting Summary

January 9, 2024 | 9:30am-3:45pm

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	Michael Kaminski	CHPA (P&G)
Angela Granum	CDER	Wendy McManus	CHPA (Sanofi)
Christine Hunt	OC	Lauren Quinn	CHPA (Haleon)
Bharat Khanna	CDER	Lisa Parks	CHPA
Theresa Michele	CDER	David Spangler	CHPA
Karen Murry	CDER	Mary Schilling	PCPC
Celia Peacock	CDER	Lynn Evans	CHPA (Kenvue)
Phong Pham	CDER		
Paul Phillips	CDER		
Kimberly Taylor	CDER		

OMUFA Facility Fee Due Date Change Proposal
Industry conveyed the potential financial impact of FDA's facility due date change from June 1st to October 1st on smaller industry firms. FDA reiterated the programmatic advantages of having the due date for annual fees under FDA's drug user fee programs be aligned with the start of the fiscal year. Industry will continue its discussion of this proposal and get back to FDA. This proposal will be discussed further at a subsequent meeting.

Target Revenue Proposal
FDA provided requested information on maintenance costs for OMUFA I Information Technology (IT) investments. FDA addressed Industry's clarifying questions on IT spending. This proposal will be discussed further at a subsequent meeting.

Product Quality Enhancement Proposal
FDA presented its product quality enhancement proposal aimed at improving FDA's understanding of the OTC monograph product landscape through targeted activities to better manage quality risks. It was emphasized that the aim of these activities was to help drive FDA's risk-based approach to surveillance inspections and lead to more informed and focused inspections. FDA addressed Industry's clarifying questions. This proposal will be discussed further at a subsequent meeting.

Innovation/Consumer Confidence in Quality Proposal
FDA presented its proposal to support innovation and consumer confidence in OTC monograph products. In this proposal, informed by public input, FDA would develop validated test methods for OTC monograph products (not associated with FDA's drug quality sampling and testing program) that could then be made public. FDA addressed Industry's clarifying questions. This proposal will be discussed further at a subsequent meeting.

Industry-FDA Engagement on Quality Proposal
FDA presented its proposal aimed at increasing engagement between FDA and industry on quality issues. FDA addressed Industry's clarifying questions. This proposal will be discussed further at a subsequent meeting.

Recharacterization and Changes to Monograph Testing Procedures
Industry presented its proposal for FDA to convene a workshop(s) or other public forum to discuss the level of detail for testing procedures in OTC monographs. Industry addressed FDA clarifying questions. This proposal will be discussed further at a subsequent meeting.

Amend Definition of Tier 2 OMOR to include Changes in Monograph Testing Procedures
Industry presented its proposal for a recommendation to amend the definition of Tier 2 OMOR as related to testing procedures. This proposal will be discussed further at a subsequent meeting.

New Meeting Type Proposal
FDA and Industry continued discussion on Industry's "Type W" meeting proposal. Industry presented requested information. FDA asked clarifying questions. Industry agreed to provide examples of questions that would be covered under this new meeting type. This proposal will be discussed the next meeting.

Industry IT Proposals
FDA and Industry continued discussion of Industry's IT proposals (proposed updates to FDA's website to capture historical monograph information about OTC monograph active ingredients; information about final orders that provide exclusivity; and information regarding active ingredients that are not subject to a final FDA "Generally Recognized As Safe and Effective" (non-GRAS/E)) determination). Industry presented requested information for its IT proposals. Internal FDA discussion with internal subject matter experts (SMEs) on resources and feasibility are ongoing. These proposals will be discussed further at a subsequent meeting.

Industry Cataloguing Paper Document (Scanning and Posting Documents) Proposals
Industry presented their proposal requesting FDA to scan/post old paper documents once initial cataloguing is completed. FDA agreed to provide requested information on the resources needed

and the timelines involved to fulfill the proposed task. This proposal will be discussed further at a subsequent meeting.

Next Steps

The agenda for January 16th meeting includes:

- FDA proposals: filing eligibility of GRASE OMORS and related extension of goal dates for proposed and final orders; face-to-face meetings definition revision
- Industry proposals: X and Y meetings, Type W meetings, and protocol assessments