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

FDA and Industry Negotiations | Meeting Summary

January 23, 2024 |9:30am-3:15pm

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	Lisa Parks	CHPA
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 provided feedback on FDA's proposal. FDA will discuss industry's feedback internally. In response to Industry's previous request for information, FDA provided information on invoicing and payment timelines as addressed in the relevant OMUFA fee rate notices and described draft guidance for industry *Assessing User Fees Under the Over-the-Counter Monograph Drug User Fee Program.* This proposal will be discussed further at a subsequent meeting.

OMUFA Facility Fee Adjustor Proposal

FDA presented its proposal for a facility fee adjuster. This proposal would provide a potential one-time adjustment of target revenue based on the number of OTC monograph drug facilities and aims to address the risk of an underfunded regulatory program should the number of facilities increase

substantially or remain above previously-anticipated levels compared to otherwise-available resourcing. This proposal will be discussed further at a subsequent meeting.

Recharacterization and Changes to Monograph Testing Procedures Proposal
FDA provided feedback on Industry's proposal to hold a workshop to discuss OTC monograph testing methods included in monographs established by the deemed final orders. FDA addressed Industry's clarifying questions on the feedback provided. This proposal will be discussed further at a subsequent meeting.

Amend Statutory Definition of Tier 2 OMOR to include Changes in Monograph Testing Procedures Proposal
FDA provided feedback on Industry's proposal to amend the statutory definition of Tier 2 OMORs to include OMORs proposing a change to or addition of certain monograph testing methods. FDA addressed Industry's clarifying questions on the feedback provided. This proposal will be discussed further at a subsequent meeting.

Product Quality Enhancement Proposals
Industry provided feedback and asked a number of clarifying questions regarding FDA's three quality-related proposals (product quality enhancement, innovation/consumer confidence in quality, and Industry-FDA engagement in quality proposals). For example, Industry sought additional information about some of FDA's current facility surveillance tools and how they are used to inform surveillance inspections. FDA provided some initial clarifications and agreed to take back Industry's feedback and questions for further consideration. FDA will discuss Industry's feedback internally. These proposals will be discussed further at a subsequent meeting.

Major Amendments Clarification Proposal
FDA presented its proposal to revise the OMUFA goals letter to indicate FDA does not intend to review major amendments to an OMOR submitted after a proposed order stemming from the OMOR is issued. FDA addressed Industry's clarifying questions. FDA agreed to provide requested information on data submission during a proposed order comment period. This proposal will be discussed further at a subsequent meeting.

Revised Definition of Face-to-Face Formal OMUFA Meeting Proposal
Industry indicated there are no further questions.

Next Steps
The agenda for January 30th meeting will be determined by the negotiation leads at their next planning meeting.