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

FDA and Industry Negotiations | Meeting Summary

November 28, 2023 | 9:30am-3:30pm

Virtual Format (Zoom)

PURPOSE

To discuss issues related to the scope of negotiations, provide an overview of OMUFA financial information, and present FDA financial proposals.

PARTICIPANTS

FDA		**Industry**	
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	Cornell Stamoran	PBOA (Catalent)
Celia Peacock	CDER	Mary Schilling	PCPC
Phong Pham	CDER		
Paul Phillips	CDER		
Kimberly Taylor	CDER		

Negotiation Scope

FDA noted that some of industry's proposals appeared outside the authorized scope of these negotiations. FDA clarified that under the statute, OMUFA reauthorization negotiations are limited to (1) the OMUFA II goals letter, e.g., goals and timeframes for accomplishing OTC monograph drug activities; and (2) proposed amendments to the OMUFA user fee statutory provisions (sections 744L, 744M, and 744N of the FD&C Act).

FDA identified industry proposals that appeared out-of-scope of negotiations and asked clarifying questions. Industry stated that it would reframe certain of its proposals in an effort to bring them within scope. FDA also asked industry to identify any scope-related concerns industry may have with FDA's proposals. Industry also noted that some of the FDA proposals seemed out of scope and sought further clarification.

OMUFA Financial Overview
FDA presented an overview of the OMUFA financial information, including fee-setting and effective stewardship efforts. The Agency reviewed fee-coverable costs under OMUFA, the process for target revenue and facility fees calculations, hiring under OMUFA, and how FDA manages the 35-week continuity set-aside to sustain operations until the annual OMUFA facility fee collections arrive late in each fiscal year.

OMUFA Facility Fee Due Date Proposal
FDA presented its proposal to move the facility fee due date from June 1st to October 1st to be in alignment with the start of the federal fiscal year (as is generally the case with other annual fees under other human drug user fee programs). FDA proposed that this change would be accompanied by corresponding modifications to the statutory timelines for publishing the annual facility fee rate notice in the *Federal Register* and for the applicable period used in determining fee liability for a fiscal year.

Target Revenue Proposal
FDA presented its proposal to establish that the base revenue be set in Year 1 of OMUFA II (FY 2026) to include the additional direct cost adjustment for FY 2025 (the final year of OMUFA I).

Next Steps
At the December 5th meeting, industry will present any scope issues they have with FDA's proposals and present their reframed proposals. The next set of industry proposals for discussion will be determined by their negotiation leads at their next planning meeting.