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

FDA and Industry Negotiations | Meeting Summary

November 14, 2023 | 9:30am-3:00pm

In-Person Format

PURPOSE

To agree on reauthorization ground rules, explain parameters for in-person and virtual environments and provide FDA and Industry perspectives on enhancements for OMUFA II.

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	Mark Gardella	PBOA (Catalent)
Celia Peacock	CDER	Mary Schilling	PCPC
Phong Pham	CDER	Gerald Masoudi	Covington & Burling
Paul Phillips	CDER		
Kimberly Taylor	CDER		

The meeting discussion was focused on the areas of interest to industry and FDA and on planning for the negotiations process.

Ground Rules for Negotiations and In-person/Virtual Environment

The ground rules governing the OMUFA reauthorization negotiations were reviewed and agreed upon by both parties. There were no edits offered for the draft that FDA presented. FDA also presented the operating processes and rules for conducting negotiations in an in-person and virtual environment. There were no comments or questions.

FDA Perspectives on Reauthorization
FDA discussed the overall experience to date in OMUFA I, emphasizing the agency's performance in meeting its commitments despite the challenges of the Coronavirus Disease 2019 (COVID-19) pandemic period. FDA also highlighted its priorities for OMUFA reauthorization, which are to ensure stable funding for the program, enhance consumer trust in the quality of over-the-counter (OTC) monograph drug products, enhance transparency of the over-the-counter monograph order (OMOR) process, and enhance regulatory efficiency and predictability. FDA briefly summarized its proposals under each priority area and answered high-level clarifying questions from industry.

Industry Perspectives on Reauthorization
Industry representatives noted that their goals for reauthorization represent an effort to build upon the initial purposes that led to the first OMUFA user fee agreement and program. In addition, Industry stated their overall priorities for reauthorization include improving transparency, enhancing communication, and allocating and focusing resources toward promoting innovation. Industry provided its recommendations to address these priorities and answered high-level clarifying questions from FDA.

Next Steps
The goals for the next meeting on November 28th will be to have more detailed discussions of FDA and industry proposals and address remaining areas for clarification.

There were no other substantive proposals, significant controversies, or differences of opinion discussed at this meeting.