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

FDA and Industry Negotiations | Meeting Summary

February 6, 2024 | 9:30am-11:20am

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	Lynn Evans	CHPA (Kenvue)
Bharat Khanna	CDER	Wendy McManus	CHPA (Sanofi)
Jennifer Maguire	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	Mary Schilling	PCPC
Paul Phillips	CDER		
Kimberly Taylor	CDER		

Product Quality Enhancement Proposals
FDA presented its response to Industry's feedback and various questions on FDA's three product-quality related proposals. Industry's questions centered on the following topic areas: FDA's perspective on the current OTC monograph product quality landscape; FDA's approach to quality surveillance of OTC monograph product manufacturing facilities; and how FDA assesses quality-related risk for its site selection model and inspections. FDA addressed Industry's additional clarifying questions. These proposals will be discussed further at a subsequent meeting.

Major Amendments Clarification Proposal
FDA provided follow-up information regarding submission of data during the comment period for proposed orders. This proposal will be discussed further at a subsequent meeting.

Next Steps
The agenda for the February 13th meeting will be determined by the negotiation leads at their next planning meeting.