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

FDA and Industry Negotiations | Meeting Summary

April 16, 2024 | 9:30am-11:55am

Virtual Format

PARTICIPANTS

FDA	Office	Industry	Organization
Ashley Boam	CDER	James Kim	ACI
Joshua Brown	OC	Katie Kramer	ACI (Hogan Lovells)
Grace Carmouze-Cunningham	CDER	Michael Bailey	CHPA
Angela Granum	CDER	Michael Kaminski	CHPA (P&G)
Theresa Michele	CDER	Barbara Kochanowski	CHPA
Karen Murry	CDER	Wendy McManus	CHPA (Sanofi)
Celia Peacock	CDER	Erin Oliver	CHPA (Haleon)
Phong Pham	CDER	David Spangler	CHPA
Paul Phillips	CDER	Cornell Stamoran	PBOA
Kimberly Taylor	CDER		

OMUFA Facility Fee Adjuster

Industry proposed having a higher number of facilities as a baseline for the adjuster given the relatively high number of facilities on the arrears list. FDA indicated they would take this increase into consideration. FDA addressed Industry's clarifying questions. This proposal will be discussed further at a subsequent meeting.

FDA Full-Time Equivalent Resources

FDA presented information on full-time equivalents (FTEs) including the OMUFA I hiring experience, available hiring authorities, and FTE-related costs. FDA addressed Industry's clarifying questions.

Advisory Committee Meeting Proposal

In response to previous discussion, FDA presented updated proposed commitment letter language under which, in certain circumstances, FDA would agree to posting advance notice of certain monograph-related Advisory Committee meetings (AdCom) on FDA's website prior to issuance of a *Federal Register* notice (FRN) announcing the meeting. It was noted that the mechanism of posting

information on the FDA website about certain upcoming AdComs prior to the FRN is fairly new. FDA addressed Industry's clarifying questions. FDA agreed to provide more information related to posting on the website ahead of the FRN.

Protocol Assessment Proposal
FDA addressed Industry's follow-up questions from previous discussions related to the CDER NextGen Portal supporting protocol assessment submissions. Industry indicated its support for moving forward with only part 1 of the proposal (FDA to use Type Y and Z meetings to provide feedback on a protocol synopsis) and not for parts 2 and 3 (related to providing FDA feedback on full protocols). Proposal 1 will be discussed further at a subsequent meeting.

Resourcing MAPPs and Guidances Proposals
Industry provided feedback on FDA's proposed resourcing for MAPPs and guidances. Industry asked for more information on current OMUFA I resources as they consider resources for OMUFA II. FDA addressed Industry's clarifying questions on both current and proposed resourcing. This topic will be discussed further at a subsequent meeting.

Next Steps
The final agenda for April 23rd meeting will be determined by the negotiation leads at their next planning meeting.