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

FDA and Industry Negotiations | Meeting Summary

March 05, 2024 | 9:00am-11:30am

Virtual Format

PARTICIPANTS

FDA	Office	Industry	Organization
Joshua Brown	OC	James Kim	ACI
Grace Carmouze-Cunningham	CDER	Katie Kramer	ACI (Hogan Lovells)
Angela Granum	CDER	Barbara Kochanowski	CHPA
Christine Hunt	OC	Erin Oliver	CHPA (Haleon)
Bharat Khanna	CDER	Michael Kaminski	CHPA (P&G)
Theresa Michele	CDER	David Spangler	CHPA
Karen Murry	CDER	Cornell Stamoran	PBOA
Celia Peacock	CDER	Mary Schilling	PCPC
Phong Pham	CDER		
Paul Phillips	CDER		

Meetings Proposals
FDA presented its counterproposal to Industry's proposed expansion and length of Type X and Type Y meetings to obtain clarification on FDA advice and other eligible topics. FDA also addressed Industry's proposal for face-to-face meetings for complex scientific or regulatory issues. FDA responded with points for consideration related to extending the length of certain formal meetings and written response only (WRO) meetings. In addition, FDA proposed 1) to add commitment letter language to related to meeting length for certain formal meetings and 2) to establish an OMUFA "Follow-up Opportunity" mechanism to address Industry's desire for follow-up clarification to FDA minutes or WROs, similar to the mechanism under PDUFA, with appropriate resourcing. FDA addressed Industry's clarifying questions. These proposals will be further discussed at a subsequent meeting.

Advisory Committee Meeting Proposal
FDA presented its response to Industry's advisory committee meeting (AdCom) proposal regarding earlier notification to affected Industry members of the date of upcoming Advisory Committees, and development of a CDER Manual of Policies and Procedures (MAPP)/guidance on the AdCom

process in part to ensure subject matter expertise presence at OMUFA-related AdComs. FDA reiterated that FDA's 2008 Guidance on Advisory Committee Meetings; Preparation and Public Availability represents FDA's current agency-wide policies and procedures and applies to AdComs broadly, including a timeframe for notice of AdComs to product sponsors in certain cases. Industry reiterated its request that FDA provide at least 5 months' notice to industry of a topic of interest and 55 business days' notice of the advisory committee date. Further, Industry reiterated its desire that OMUFA sponsors of an ingredient that is the subject of an advisory committee receive "sponsor" treatment for purposes of the guidance. FDA proposed commitment letter language indicating it will strive to issue the *Federal Register* notice announcing an AdCom well in advance of the meeting date, so that all interested parties will have time to prepare. In addition, FDA indicated it does not have enough experience with OMOR AdComs to develop the industry-proposed MAPP or guidance. FDA also indicated that it already has a process to ensure appropriate expertise at AdComs. FDA addressed Industry's clarifying questions. This proposal will be further discussed at a subsequent meeting.

Changes in Monograph Testing Procedures Proposal
In a follow-up to Industry's question regarding whether Tier 2 OMORs could be submitted via the CDER NextGen Portal given the expected smaller content of a Tier 2 OMOR, FDA indicated that the portal was designed to allow both Tier 1 and Tier 2 OMOR submissions, and FDA provided an overview of the portal submission process. This proposal will be further discussed at a subsequent meeting.

IT Platform – Information on Proposed FDA Website Regarding Final Orders Providing Exclusivity Proposal
FDA presented a potential approach to address Industry's desire to have monograph drug exclusivity information publicly posted after issuance of a final order affording exclusivity. FDA addressed Industry's clarifying questions. This proposal will be further discussed at a subsequent meeting.

Filing Eligibility Determination for GRASE OMORS and Related Extension of Goal Dates for Proposed and Final Order Proposal
Industry provided a counterproposal to FDA's proposal for a timeline on filing eligibility determinations for OMORs proposing new monograph drug active ingredients and addressed FDA's clarifying questions. This proposal will be further discussed at a subsequent meeting.

Next Steps
The final agenda for the March 12th will be determined by the negotiation leads at their next planning meeting.