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

FDA and Industry Negotiations | Meeting Summary

January 16, 2024 |9:30am-2:55pm

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	Michael Kaminski	CHPA (P&G)
Angela Granum	CDER	Wendy McManus	CHPA (Sanofi)
Christine Hunt	OC	Erin Oliver	CHPA (Haleon)
Theresa Michele	CDER	Lisa Parks	CHPA
Karen Murry	CDER	David Spangler	CHPA
Celia Peacock	CDER	Mark Gardella	PBOA
Phong Pham	CDER	Mary Schilling	PCPC
Paul Phillips	CDER		
Kimberly Taylor	CDER		

Filing Eligibility Determination for GRASE OMORS and related Extension of Goal Dates for Proposed and Final Order Proposal
FDA presented its proposal to revise the OMUFA goals letter to align with the statute regarding filing eligibility determination for OMORs proposing new monograph active ingredients. The proposal would enable necessary time for OMOR review activities by extending the related goal dates for issuing proposed and final orders. FDA addressed Industry's clarifying questions. This proposal will be discussed further at a subsequent meeting.

Revised Definition of Face-to-Face Formal OMUFA Meeting Proposal
FDA presented its proposal to revise the "Responses to Meeting Requests" section of the OMUFA goals letter to include language indicating face-to-face meetings can either be in-person or virtual with cameras on. Industry asked clarifying questions. FDA addressed Industry's clarifying questions. This proposal will be discussed further at a subsequent meeting.

Public Comment Period and Related Extension of Goal date for Issuing Final Order Proposal
Industry indicated there are no further questions.

Meeting Requests to NextGen Portal Proposal
Industry indicated there are no further questions.

IT Platform – Information on FDA Website Regarding Final Orders Providing Exclusivity Proposal
Industry provided requested modifications to the types of information Industry requests that FDA agree to post. Industry addressed FDA's clarifying questions. Both FDA and Industry will provide follow-up information on this proposal. This proposal will be discussed further at a subsequent meeting.

Type X and Type Y Meetings Proposal
Industry presented its proposal for a process to extend the meeting time for Type X and Type Y meetings when there are multiple concepts in the ingredient category or multiple ingredients impacted. Industry addressed FDA's clarifying questions. There was general discussion around the adequacy of existing meetings to address the various kinds of questions and development activities for which Industry might request feedback from FDA. This proposal will be discussed further at a subsequent meeting.

Face-to-Face Meetings for Complex Scientific or Regulatory Issues Proposal
Industry presented its proposal for a process for granting face-to-face meetings for complex regulatory and/or scientific issues. Industry addressed FDA's clarifying questions. This proposal will be discussed further at a subsequent meeting.

Advisory Committee Meetings Proposal
Industry presented its proposal to have greater certainty around timeframes for notifications for Advisory Committees, have FDA clarify the AdCom process related to an OMOR in a MAPP/guidance, and to have FDA ensure subject matter experts are present at AdCom meetings. This proposal will be discussed further at a subsequent meeting.

Next Steps
The agenda for January 23rd meeting will include:

- FDA proposals: facility fee adjustor, major amendment clarification, follow-up on facility fee due date change, and follow-up to Industry's testing procedures proposals
- Industry proposals: follow-up on FDA's facility fee due date change and product quality proposals