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

FDA and Industry Negotiations | Meeting Summary

May 29, 2024 | 2:00pm-3:00pm

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	Mikel Bailey	CHPA
Angela Granum	CDER	Barbara Kochanowski	CHPA
Christine Hunt	OC	Michael Kaminski	CHPA (P&G)
Bharat Khanna	CDER	Wendy McManus	CHPA (Sanofi)
Theresa Michele	CDER	Erin Oliver	CHPA (Haleon)
Karen Murry	CDER	David Spangler	CHPA
Celia Peacock	CDER	-	-
Paul Phillips	CDER	-	-
Kimberly Taylor	CDER	-	-

OMUFA Facility Fee Adjuster Proposal and Arrears-Related Information

FDA presented draft commitment letter language that provided for more transparency regarding firms in arrears as part of the annual OMUFA financial report to Congress and other reporting on FDA's website. Information of interest to industry includes the number of facilities in arrears, whether these firms are foreign or domestic, the number of Dunning letters FDA sends on a quarterly basis, and the number of facilities that have paid facility fees in the prior fiscal year. FDA addressed Industry's clarifying questions. Industry indicated support for this proposal.

Product Quality Proposal

There was discussion of FDA's updated proposal that included Industry's comments on

resources, FDA's system for cataloging facility information, and draft wording of FDA's deliverables for the commitment letter. Based on these comments, FDA presented updated draft commitment language. Industry indicated support for this proposal, pending review of the full draft commitment letter.

Advisory Committee Meeting Proposal

FDA presented their updated counterproposal on advanced notification for certain advisory committee (AC) meetings. The proposal indicated that FDA would intend to post on its website notice of a specific subset of OTC monograph-related AC meetings at least 100 business days in advance of the meeting. This subset includes planned AC meetings that do not intend to address a safety issue and for which the existing policy on advance notice in FDA's 2008 Advisory Committee Meetings Guidance does not apply. FDA addressed Industry's clarifying questions. Industry provided initial feedback on wording. FDA will take Industry's feedback into consideration. Industry will discuss this language internally.

Draft OMUFA II Commitment Letter

FDA will populate the draft commitment letter shell with agreed-upon dates and language and send to Industry.

Next Steps

FDA to send Industry the draft commitment letter for review. The June 4th meeting will cover any remaining questions or issues.