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

FDA and Industry Negotiations | Meeting Summary

December 12, 2023 | 9:30am-3:45pm

Virtual Format (Zoom)

PARTICIPANTS

FDA		**Industry**	
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	Lauren Quinn	CHPA (Haleon)
Bharat Khanna	CDER	Lisa Parks	CHPA
Theresa Michele	CDER	David Spangler	CHPA
Celia Peacock	CDER	Cornell Stamoran	PBOA (Catalent)
Phong Pham	CDER	Mary Schilling	PCPC
Paul Phillips	CDER		
Kimberly Taylor	CDER		

Industry's Reframed Proposals
Industry presented their reframed proposals for FDA to consider in terms of whether they were within scope of these negotiations. Industry answered FDA's clarifying questions and made some slight modifications. FDA and industry then reached agreement that the updated list of proposals industry was sharing at the meeting were within scope for OMUFA II negotiations.

FDA Proposals
FDA addressed comments and answered clarifying questions. Industry agreed the list of FDA proposals were within scope.

Formal Meeting Request Submissions via NextGen Portal
FDA presented its proposal to have submitters use the existing NextGen Portal (or its successor) to submit their formal meeting requests. By using the NextGen Portal rather than sending requests via email, FDA anticipates risks such as processing delays and records management issues will be mitigated. FDA answered Industry's clarifying questions.

Public Comment Period and Extension of Goal date for Final Orders
FDA presented its proposal to update the existing OMUFA goals letter language regarding the public comment period for proposed orders to include a specified length of time for an extension of the public comment period. FDA proposed that if the public comment period is extended, then the final order goal date would also be extended by the same length of time. Industry asked clarifying questions.

Cataloguing of Paper Documents
Industry presented its proposal to expand the existing cataloguing of historical monograph-related paper documents to include public search and sorting capabilities. FDA asked clarifying questions and noted it would discuss this proposal with internal subject matter experts to determine feasibility and resources needed.

New Meeting Type
Industry presented its proposal to add a new formal meeting type "W" analogous to the "Type D" meetings under the PDUFA VII commitment letter. FDA asked clarifying questions and requested additional information to better understand the potential scenarios and criteria for this new meeting type. Industry agreed to provide follow-up information.

Next Steps
The agenda for December 19th will be determined by the negotiation leads at their next planning meeting.