



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

FDA and Industry Negotiations | Meeting Summary

June 4, 2024 | 10:30am-10:50am

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	Mike Bailey	CHPA
Angela Granum	CDER	Barbara Kochanowski	CHPA
Christine Hunt	OC	Wendy McManus	CHPA (Sanofi)
Theresa Michele	CDER	David Spangler	CHPA
Celia Peacock	CDER	-	-
Paul Phillips	CDER	-	-
Kimberly Taylor	CDER	-	-

Draft OMUFA II Commitment Letter

FDA presented an overview of the draft commitment letter which contained previously agreed upon language. It was noted that the FDA changed the existing OMUFA commitment letter format to align with the format currently used by the BsUFA, GDUFA, and PDUFA commitment letters. FDA addressed industry's clarifying questions. Industry indicated it would review and send their initial comments on June 5th.

Next Steps

Industry to send FDA initial comments on draft commitment letter via email on June 5th.