



Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Steering Committee Meeting | Meeting Summary

June 4th, 2021 | 1:00pm-3:00pm

Virtual Format

PURPOSE

To discuss drafted commitment letter language for BsUFA III.

PARTICIPANTS

FDA

Josh Barton	CDER
Leslie Bryant	OC
Alonza Cruse	ORA
Emily Ewing	CDER
Laurie Graham	CDER
Andrew Kish	CDER
Steve Kozlowski	CDER
Paul Phillips	CDER
Carol Rehkopf	CDER
Chris Sese	CDER
Mary Ann Slack	CDER
Kim Taylor	CDER
Mary Thanh Hai	CDER
Sarah Yim	CDER

Industry

Hillel Cohen	AAM (Sandoz)
David Gaugh	AAM
Lisa Parks	AAM
Cory Wohlbach	AAM (Teva)
Linda Bowen	BIO (Seagen)
Leah Christl	BIO (Amgen)
Camelia Thompson	BIO
Ann Begley	Biosimilars Forum (Wiley)
Trevor LaSalvia	Biosimilars Forum (Wiley)
Erika Satterwhite	Biosimilars Forum (Viatris)
Nathalie Yanze	Biosimilars Forum (Coherus)
Ryan Kaat	PhRMA
Laura McKinley	PhRMA (Pfizer)
Lucy Vereshchagina	PhRMA

Commitment Letter Language

Industry reviewed suggested changes to the draft commitment letter FDA provided. FDA asked clarifying questions about the proposed changes to language about supplement categories and regulatory science. FDA and Industry caucused independently and then returned to confirm edits to the commitment letter language. FDA agreed to make additional edits as discussed and provide a revised draft of the commitment letter to Industry.

There were no other substantive proposals, significant controversies, or differences of opinion discussed at this meeting.