Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Steering Committee Meeting | Meeting Summary

June 1st, 2021 | 2:00pm-4:00pm

Virtual Format

PURPOSE

To discuss drafted commitment letter language for BsUFA III.

PARTICIPANTS

FDA		Industry	
Josh Barton	CDER	Hillel Cohen	AAM (Sandoz)
Leslie Bryant	OC	David Gaugh	AAM
Alonza Cruse	ORA	Lisa Parks	AAM
Emily Ewing	CDER	Cory Wohlbach	AAM (Teva)
Alison Falb	CDER	Linda Bowen	BIO (Seagen)
Laurie Graham	CDER	Leah Christl	BIO (Amgen)
Andrew Kish	CDER	John Murphy	BIO
Steve Kozlowski	CDER	Camelia Thompson	BIO
Paul Phillips	CDER	Ann Begley	Biosimilars Forum (Wiley)
Carol Rehkopf	CBER	Trevor LaSalvia	Biosimilars Forum (Wiley)
Chris Sese	CDER	Erika Satterwhite	Biosimilars Forum (Viatris)
Mary Ann Slack	CDER	Nathalie Yanze	Biosimilars Forum (Coherus)
Peter Stein	CDER	David Ceryak	PhRMA (Eli Lilly)
Kim Taylor	CDER	Ryan Kaat	PhRMA
Mary Thanh Hai	CDER	Laura McKinley	PhRMA (Pfizer)
Sarah Yim	CDER	Lucy Vereshchagina	PhRMA

FDA and Industry agreed upon overall resources estimates and management of the carryover balance via email.

Commitment Letter Language

FDA reviewed the draft commitment letter language for BsUFA III and noted key changes from the BsUFA II commitment letter. Industry asked clarifying questions about the language for supplement categories, meeting management metrics, and regulatory science topic areas and timelines. FDA responded to Industry's questions and committed to providing updates to the draft language as appropriate.

Industry agreed to provide additional comments on FDA's draft commitment letter language via email. The goals for the next meeting on June 4th will be to continue discussing draft language for the BsUFA III commitment letter.

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