Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Steering Committee Meeting | Meeting Summary

May 19th, 2021 | 11:30pm-1:00pm

Virtual Format

PURPOSE

To revisit proposals related to guidance development and regulatory science, and to discuss resource estimates.

PARTICIPANTS

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

Guidance Development

FDA reviewed updates to their proposal to support scientific research and guidance development around interchangeability, including timelines for key deliverables. Industry asked clarifying questions about the rationale for the timelines and proposed alternate timelines. FDA and Industry agreed to finalize deliverables and timelines in a subsequent meeting.

Regulatory Science

Industry presented a counterproposal for a pilot regulatory science program with clear demonstration projects and deliverables. FDA indicated general agreement with the proposed structure and topic areas for demonstration projects. FDA committed to review the proposal and provide a resource estimate.

Resource Estimates
FDA provided a high-level overview of estimated resources associated with the previously negotiated BsUFA III topics. Industry asked clarifying questions about the rationale for FDA's resource estimates. FDA responded to the questions and explained the estimation methodology. FDA and Industry discussed the distribution of resources across BsUFA III and use of the BsUFA II carryover balance.

FDA and Industry agreed to further conversations about administrative and technical fixes and human factors and URRA via email. The goals for the next meeting on May 25th will be to continue discussing guidance development, regulatory science, and resources.

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