Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Steering Committee Meeting | Meeting Summary

May 25th, 2021 | 2:00pm-4:00pm

Virtual Format

PURPOSE

To discuss overall fee and resource estimates and revisit regulatory science and administrative and technical fixes.

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
Lubna Merchant	CDER	Ann Begley	Biosimilars Forum (Wiley)
Paul Phillips	CDER	Trevor LaSalvia	Biosimilars Forum (Wiley)
Carol Rehkopf	CBER	Erika Satterwhite	Biosimilars Forum (Viatris)
Chris Sese	CDER	Nathalie Yanze	Biosimilars Forum (Coherus)
Mary Ann Slack	CDER	David Ceryak	PhRMA (Eli Lilly)
Peter Stein	CDER	Ryan Kaat	PhRMA
Kim Taylor	CDER	Laura McKinley	PhRMA (Pfizer)
Mary Thanh Hai	CDER	Lucy Vereshchagina	PhRMA
Sarah Yim	CDER		

Overall Fee & Resource Estimates

FDA reviewed the overall resource estimate for topics as presently negotiated and explained the rationale for estimated fees across BsUFA III. Industry asked clarifying questions about the methodology and requested that FDA share the information with additional assumptions included. Industry also inquired about FDA's rationale for resource estimates on specific topics, including human factors and URRA timelines, meeting management, and regulatory science. FDA and Industry agreed to resources for regulatory science, supplements, and human factors and URRA timelines. The parties agreed to continue discussing resources for meeting management.

Regulatory Science
FDA indicated agreement with Industry's regulatory science counterproposal, presented in the previous meeting. FDA and Industry reviewed and discussed counterproposals regarding deliverables and timelines for the regulatory science pilot. FDA agreed to prepare updated language for Industry to review offline.

Administrative & Technical Fixes
Industry indicated that, following FDA's last written response to Industry questions, they had no further questions regarding administrative and technical fixes. Industry agreed to the proposed administrative and technical fixes.

FDA agreed to provide draft commitment letter language offline. The goals for the next meeting on June 1st will be to finalize overall resource estimates and management of the carryover balance.

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