Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Steering Committee Meeting | Meeting Summary

April 13th, 2021 | 2:00pm-4:00pm

Virtual Format

PURPOSE

To discuss proposals related to regulatory science and Human Factors and URRA timelines, and to revisit supplements and labeling for product safety updates.

PARTICIPANTS

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

Regulatory Science

FDA presented their proposal regarding BsUFA regulatory science. FDA highlighted the success of the GDUFA Regulatory Science Program and identified objectives for a proposed BsUFA regulatory science program specific to facilitating more efficient biosimilar and interchangeable product development and enhancing regulatory decision-making. FDA and Industry discussed aspects of the proposal, including opportunities for Industry engagement, program design, and resources. Industry agreed to discuss regulatory science internally and revisit in a future meeting.

Human Factors and URRA Timelines
FDA presented their proposal regarding timelines for reviewing Human Factors protocols and URRA. Industry asked clarifying questions about the proposal, which FDA responded to. FDA agreed to follow up with language clarification and details on the scope of URRA review. FDA and Industry discussed suggested resources to meet the proposed timelines.

Supplements and Labeling for Product Safety Updates
FDA presented their response to Industry's previously presented proposal regarding labeling for product safety updates. FDA and Industry discussed implications of the proposal, and Industry agreed to consider FDA's proposal and present their response in a future meeting. FDA and Industry also discussed Industry's follow-up questions regarding FDA's supplement proposal presented on March 30th. FDA and Industry agreed to revisit supplement proposals in more detail the following week.

The goals for the next meeting on April 20th will be to revisit supplements, guidance development, and best practices for application review.

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