Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Steering Committee Meeting | Meeting Summary

April 27th, 2021 | 2:00pm-4:00pm

Virtual Format

PURPOSE

To revisit proposals related to information technology, supplements and labeling for product safety updates, meeting management, and finance and staffing enhancements.

PARTICIPANTS

FDA		Industry	
Josh Barton	CDER	Hillel Cohen	AAM (Sandoz)
Leslie Bryant	OC	David Gaugh	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	Camelia Thompson	BIO
Leila Hann	CDER	Ryan Fournier	Biosimilars Forum (Wiley)
Andrew Kish	CDER	Trevor LaSalvia	Biosimilars Forum (Wiley)
Steve Kozlowski	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		

Information Technology

FDA reviewed their responses to Industry's proposals on a data and technology modernization strategy and monitoring and modernizing the Electronic Submissions Gateway. FDA and Industry discussed resources associated with these proposals. FDA reviewed their proposal to leverage cloud technology to progress regulatory digital transformation. FDA explained their proposal for a demonstration project to support cloud innovation specific to biosimilar applications. FDA and Industry discussed the intent and potential topic of the demonstration project and resources for the overall proposal. Industry agreed to consider the demonstration project and the resource estimates for all proposals.

Supplements and Labeling for Product Safety Updates
FDA presented an updated proposal on supplement categories and timelines. FDA and Industry discussed terminology and agreed to reconsider use of specific terms. Industry inquired about the scope of the proposal. FDA confirmed that manufacturing supplements are out of scope and agreed to consider further the scope of the proposal. FDA noted that their supplement proposal is contingent on resources. Industry agreed to consider FDA's proposed supplement categories and timelines. Industry did not agree to FDA's response to Industry's proposal regarding product safety labeling updates and committed to preparing a counterproposal.

Meeting Management
FDA presented their responses to Industry's meeting management proposals. FDA and Industry discussed proposed modifications relating to BIA meetings. Industry inquired about the scheduling timeline and the process for determining meeting format for a proposed new BPD meeting type. Industry also inquired about FDA's proposed timeline relating to a modified Type 4 meeting process, and FDA explained the complexities associated with these meetings. FDA indicated general alignment with Industry on clarifying FDA feedback and comments and updating respective guidance. FDA noted that all the proposals are dependent on appropriate resources.

Finance and Staffing Enhancements
FDA presented an overview of the previously presented proposals relating to finance and staffing enhancements. FDA and Industry discussed outstanding clarifying questions about the proposals. FDA also provided resource estimates for proposals regarding resource capacity planning and hiring and retention. Industry agreed to consider the proposals and resources.

The goals for the next meeting on May 4th will be to revisit supplements and labeling for product safety updates, meeting management, guidance development, and best practices during application review.

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