Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Steering Committee Meeting | Meeting Summary

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

Virtual Format

PURPOSE

To revisit proposals related to supplements and labeling for product safety updates, meeting management, best practices during application review, and guidance development.

PARTICIPANTS

FDA		Industry	
Leslie Bryant	OC	Hillel Cohen	AAM (Sandoz)
Alonza Cruse	ORA	David Gaugh	AAM
Emily Ewing	CDER	Lisa Parks	AAM
Alison Falb	CDER	Cory Wohlbach	AAM (Teva)
Laurie Graham	CDER	Linda Bowen	BIO (Seagen)
Leila Hann	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	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		

Supplements and Labeling for Product Safety Updates

FDA reviewed refined language on supplement categories and timelines. Industry generally agreed to the categories and timelines and requested that FDA provide draft commitment letter language and a resource estimate. FDA committed to preparing the materials. Industry proposed timelines for product safety labeling updates, and FDA agreed to consider the proposed timelines.

Meeting Management

FDA responded to Industry's questions regarding the format and timing for a new BPD meeting for targeted feedback. Industry indicated general agreement with FDA's position. FDA also reviewed

their proposal regarding the Type 4 meeting process and responded to Industry's clarifying questions. Industry agreed to consider the FDA proposal further.

Best Practices During Application Review
FDA presented their updated proposal on best practices during application review. FDA and Industry discussed specifics for continued follow-up on the implementation of best practices in BsUFA III. Industry indicated agreement with FDA's proposal.

Guidance Development
FDA and Industry discussed the scope and nature of guidance documents for potential inclusion in the biosimilar user fee commitments. FDA acknowledged the importance of interchangeability topics and presented a proposal to support scientific research and guidance development around interchangeability. Industry requested that FDA provide additional details about the proposal in a subsequent meeting. Industry also answered FDA's clarifying questions about Industry's guidance priorities.

The goals for the next meeting on May 11th will be to continue discussing supplements and labeling for product safety updates, meeting management, and guidance development, and to revisit regulatory science.

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