Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Steering Committee Meeting | Meeting Summary

April 20th, 2021 | 2:00pm-4:00pm

Virtual Format

PURPOSE

To revisit proposals related to supplements (excluding labeling for product safety updates), guidance development, and best practices for application review.

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)
Leila Hann	CDER	John Murphy	BIO
Andrew Kish	CDER	Camelia Thompson	BIO
Steve Kozlowski	CDER	Ryan Fournier	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		

Supplements (excluding Labeling for Product Safety Updates)

FDA and Industry shared updated thinking on supplement proposals. Industry highlighted the importance of clear and predictable timelines for supplement review. Industry also clarified that their proposal applies only to labeling supplements. FDA described the complexity of supplement categories and emphasized the need for careful consideration of categories and review timelines. FDA agreed to provide additional clarity on the Agency's proposed supplement categories and review timelines.

Guidance Development
FDA presented a response to Industry's proposal on guidance development, including holding a workshop during BsUFA III to discuss policy priorities for the program. Industry highlighted their interest in early timelines for guidance. FDA agreed to consider Industry's feedback.

Best Practices for Application Review
FDA presented a response to Industry's proposal on best practices for application review. FDA and Industry agreed that accelerating the timeline for discussions about best practices is mutually beneficial. FDA and Industry discussed opportunities for additional follow-up discussion on implementation of best practices into FDA documents and procedures.

The goals for the next meeting on April 27th will be to revisit supplements and labeling for product safety updates, meeting management, information technology, and financial and staffing enhancements.

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