Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Steering Committee Meeting | Meeting Summary

March 30th, 2021 | 2:00pm-4:00pm

Virtual Format

PURPOSE

To discuss proposals related to supplements, labeling for product safety updates, and guidance development, and to provide an update on FDA's Five-Year Financial Plan for BsUFA II.

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	John Murphy	BIO
Leila Hann	CDER	Camelia Thompson	BIO
Andrew Kish	CDER	Ann Begley	Biosimilars Forum (Wiley)
Steve Kozlowski	CDER	Trevor LaSalvia	Biosimilars Forum (Wiley)
Neel Patel	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		

Supplements and Labeling for Product Safety Updates

FDA presented their proposal on supplement categorization and review timelines and provided rationale for the proposed timelines. Industry asked clarifying questions about the supplement categories proposed by FDA. FDA responded and agreed to provide additional details and examples in a follow-up meeting. Industry then presented their proposals on supplement categorization, review timelines, and labeling for product safety updates. FDA discussed the difficulty of assessing the impact of changes to supplement timelines, given that biosimilar supplement review is a relatively new function and it is difficult to predict the volume and nature of topics that may need to

be addressed in supplements. FDA and Industry also discussed the allocation of work for those assigned to labeling reviews. FDA expressed concern that in some cases, labeling reviews for biosimilars may be complex. FDA agreed to further research timelines and resources for future discussion. Industry agreed to consider FDA's comments.

Guidance Development
Industry presented their proposals on guidance development for CMC post-approval manufacturing changes and interchangeability topics. Industry expressed interest in guidance development occurring early in BsUFA III. FDA noted interest in similar topics and agreed to assess the feasibility of addressing these guidance topics and timelines in BsUFA III.

Update on Five-Year Financial Plan
FDA acknowledged the BsUFA II commitment for FDA to publish an annual update to the BsUFA II Five-Year Financial Plan. FDA noted that the 2021 update is now public and highlighted some of the key takeaways in the update.

The goals for the next meeting on April 6th will be to discuss best practices in application review, financial and staffing topics, and information technology.

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