Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Steering Committee Meeting | Meeting Summary

March 23rd, 2021 | 2:00pm-4:00pm

Virtual Format

PURPOSE

To confirm the schedule for negotiation topics, to review FDA and Industry proposals on inspection topics, and to further explore and clarify Industry's proposals for meeting management.

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	Laura McKinley	PhRMA (Pfizer)
Mary Ann Slack	CDER	Lucy Vereshchagina	PhRMA
Peter Stein	CDER		
Kim Taylor	CDER		
Eva Temkin	CDER		
Mary Thanh Hai	CDER		
Sarah Yim	CDER		

Schedule for Negotiation Topics

FDA presented the overall timeline for BsUFA reauthorization and the schedule for discussing topics presented by FDA and Industry during the kickoff meeting. FDA and Industry agreed to the proposed schedule.

Inspection Topics
Industry reviewed their proposal about issuing guidance during BsUFA III on the use of alternative tools to assess manufacturing facilities in pending applications. FDA had no questions and tentatively agreed to the proposal. FDA reviewed their proposal about pre-licensure inspection notification. Industry had no questions and agreed to review the proposal following the meeting.

Meeting Management
Industry presented several proposals related to meeting management, including modifying the description of BIA meetings, establishing a new BPD meeting type for focused, targeted questions, modifying the Type 4 meeting process, clarifying FDA feedback and comments, and updating respective guidance with any changes to meeting procedures. FDA and Industry discussed the rationale and scope of the proposed meeting management changes along with how the current meeting types are being used by sponsors. FDA asked clarifying questions and requested examples for several of the proposed changes. Industry agreed to provide such examples. FDA and Industry agreed to continue discussing the meeting management proposals at a subsequent negotiation session.

The goals for the next meeting on March 30th will be to discuss supplement review and guidance development. FDA will also provide an update on the Five-Year Financial Plan.

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