Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Steering Committee Meeting | Meeting Summary

May 11th, 2021 | 2:00pm-4:00pm

Virtual Format

PURPOSE

To revisit proposals related to supplements and labeling for product safety updates, meeting management, guidance development, and regulatory science.

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)
Andrew Kish	CDER	Leah Christl	BIO (Amgen)
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)
Peter Stein	CDER	David Ceryak	PhRMA (Eli Lilly)
Kim Taylor	CDER	Ryan Kaat	PhRMA
Mary Thanh Hai	CDER	Laura McKinley	PhRMA (Pfizer)
Sarah Yim	CDER	Lucy Vereshchagina	PhRMA

Supplements and Labeling for Product Safety Updates

FDA reviewed refined language on supplement categories and timelines, including labeling for product safety updates. Industry agreed with the revised language. FDA committed to proposing resources for supplement review in a subsequent meeting.

Meeting Management

FDA and Industry reviewed previously-proposed modifications to the Type 4 meeting process and agreed on the modifications. FDA provided their position on scheduling timelines for meetings, and Industry accepted FDA's position. FDA and Industry also discussed and identified meeting management metrics that would be useful to collect and report. FDA committed to proposing resources for meeting management, for discussion in a subsequent meeting.

Guidance Development
FDA presented a proposal to support scientific research and guidance development around interchangeability, with additional details as requested in the previous meeting. Industry asked clarifying questions about FDA's proposed approach, which FDA responded to. Industry committed to considering the approach and providing a response in a subsequent meeting. FDA committed to proposing timelines for key deliverables associated with the proposal.

Regulatory Science
FDA reviewed their proposal to pilot a regulatory science program in BsUFA III and discussed the objectives of the proposed pilot. Industry indicated support for a regulatory science pilot with defined research topics and deliverables. Industry also agreed to think further about topics of interest for regulatory science research. Industry inquired about evaluation of the pilot program and FDA's intended scale of the pilot. FDA agreed to provide additional details about pilot assessment and scale in a subsequent meeting.

The goals for the next meeting on May 19th will be to continue discussing guidance development and regulatory science and, as needed, to revisit administrative and technical fixes, information technology, and human factors and URRA timelines.

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