Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Steering Committee Meeting | Meeting Summary

April 6th, 2021 | 2:00pm-4:00pm

Virtual Format

PURPOSE

To discuss proposals related to best practices in application review, information technology, finance and hiring and retention, and administrative and technical fixes for BsUFA III.

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	Ann Begley	Biosimilars Forum (Wiley)
Steve Kozlowski	CDER	Trevor LaSalvia	Biosimilars Forum (Wiley)
Paul Phillips	CDER	Erika Satterwhite	Biosimilars Forum (Viatris)
Carol Rehkopf	CBER	Nathalie Yanze	Biosimilars Forum (Coherus)
Chris Sese	CDER	David Ceryak	PhRMA (Eli Lilly)
Mary Ann Slack	CDER	Ryan Kaat	PhRMA
Peter Stein	CDER	Laura McKinley	PhRMA (Pfizer)
Kim Taylor	CDER	Lucy Vereshchagina	PhRMA
Mary Thanh Hai	CDER		
Sarah Yim	CDER		

Best Practices in Application Review

Industry reviewed their proposal on best practices in application review, which included public engagement with FDA and updates to FDA documents. FDA asked clarifying questions about expected topics for public engagement. FDA and Industry discussed options for streamlining the proposal.

Information Technology
Industry reviewed their proposals regarding the development of a Data and Technology Modernization Strategy and monitoring and modernization of the Electronic Submission Gateway (ESG). Industry answered FDA's clarifying question about the venue for providing updates on the Data Technology and Modernization Strategy. FDA then presented their proposal to support cloud-based technology and conduct a demonstration project specific to biosimilars. FDA and Industry discussed possible pathways for identifying and prioritizing demonstration project(s). FDA presented resource estimates and the proposed timeline for their proposal. Industry agreed to consider the proposal for future discussion.

Finance and Hiring and Retention
FDA provided background on the financial flexibilities built into BsUFA II to help manage program uncertainties, which FDA expects will continue in BsUFA III. FDA then presented their proposals to advance the Agency's resource capacity planning capability and improve hiring and retention of review staff. FDA responded to Industry's clarifying questions about the purpose and scope of the proposals. After FDA's presentation, Industry presented their proposals on resource capacity planning, financial transparency and accountability, management of the carryover balance, and hiring and retention of review staff. Industry answered clarifying questions from FDA. FDA and Industry agreed to review the respective proposals.

Administrative and Financial Technical Fixes
FDA provided a summary of proposed administrative and technical changes to clarify and improve the administration of aspects of the user fee program. FDA noted that they would provide additional details following the meeting. Industry asked for examples associated with the technical changes and FDA agreed to provide such examples. Industry agreed to review the proposal in more detail.

The goals for the next meeting on April 13th will be to discuss regulatory science, human factors and URRA timelines, and supplements and labeling for product safety updates.

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