Biosimilar User Fee Act (BsUFA) Reauthorization

FDA and Industry Steering Committee Meeting | Meeting Summary

March 16th, 2021 | 1:00pm-4:00pm

Virtual Format

PURPOSE

To review reauthorization ground rules, explain parameters for virtual environment and provide FDA and Industry perspectives on enhancements 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)
Laurie Graham	CDER	Linda Bowen	BIO (Seagen)
Leila Hann	CDER	Leah Christl	BIO (Amgen)
Andrew Kish	CDER	John Murphy	BIO
Steve Kozlowski	CDER	Camelia Thompson	BIO
Neel Patel	CDER	Ann Begley	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	Laura McKinley	PhRMA (Pfizer)
Kim Taylor	CDER	Lucy Vereshchagina	PhRMA
Eva Temkin	CDER		
Mary Thanh Hai	CDER		
Sarah Yim	CDER		

The meeting discussion was focused on issues of interest to Industry and FDA and on planning for the negotiation process.

Ground Rules for Negotiations and Virtual Environment

The ground rules governing the BsUFA III reauthorization negotiations were reviewed and agreed-upon by industry representatives and FDA prior to the meeting. FDA reviewed these ground rules at the meeting, and no further questions arose. FDA also presented operating processes and rules for conducting negotiations in a virtual environment. There were no comments or questions.

FDA Perspectives on Reauthorization
FDA discussed the overall experience to date in BsUFA I and II. The Agency highlighted that although Biosimilar Development Program enrollment continues to grow, application submissions vary from year to year. FDA noted that while they generally meet core review performance goals, meeting management continues to be a challenge. FDA explained that the flexible independent user fee structure established in BsUFA II has been effective in managing fluctuations in fee collections and maintaining predictable application and program fees amounts. FDA highlighted the Agency's overall goals for BsUFA III reauthorization, which are to ensure stable funding for the program, enhance regulatory predictability and efficiency, enhance operational capabilities, efficiency, and agility, and address information and scientific gaps to facilitate more efficient development. FDA shared its proposed enhancements for BsUFA III related to regulatory science, supplements, human factors protocols and use related risk analysis, information technology, inspections, and finance. FDA briefly summarized each of its proposals. There were no clarifying questions.

Industry Perspectives on Reauthorization
The collective industry representatives presented proposals addressing topics such as: FDA-Industry communication and meetings, supplement review, labeling, guidance development, inspections, information technology, and financial accountability and staffing. Industry briefly summarized each of its proposals and responded to clarifying questions from FDA. Biosimilars Council/AAM and Biosimilars Forum presented on regulatory science; PhRMA and BIO did not support the proposal on regulatory science. FDA and Industry noted topic areas with overlapping proposals.

Next Steps
The goals for the next meeting on March 23rd will be to establish a schedule for discussing topics and begin more detailed discussions of FDA and Industry proposals.

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