Biosimilar User Fee Act (BsUFA) Reauthorization
FDA and Industry Steering Committee Meeting | Meeting Summary
April 13th, 2021 | 2:00pm-4:00pm
Virtual Format

PURPOSE
To discuss proposals related to regulatory science and Human Factors and URRA timelines, and to revisit supplements and labeling for product safety updates.

PARTICIPANTS

**FDA**
- Josh Barton, CDER
- Leslie Bryant, OC
- Alonza Cruse, ORA
- Emily Ewing, CDER
- Alison Falb, CDER
- Laurie Graham, CDER
- Leila Hann, CDER
- Andrew Kish, CDER
- Steve Kozlowski, CDER
- Lubna Merchant, CDER
- Paul Phillips, CDER
- Carol Rehkopf, CBER
- Chris Sese, CDER
- Mary Ann Slack, CDER
- Peter Stein, CDER
- Kim Taylor, CDER
- Mary Thanh Hai, CDER
- Sarah Yim, CDER

**Industry**
- David Gaugh, AAM
- Lisa Parks, AAM
- Cory Wohlbach, AAM (Teva)
- Linda Bowen, BIO (Seagen)
- Leah Christl, BIO (Amgen)
- John Murphy, BIO
- Camelia Thompson, BIO
- Ryan Fournier, Biosimilars Forum (Wiley)
- Trevor LaSalvia, Biosimilars Forum (Wiley)
- Erika Satterwhite, Biosimilars Forum (Viatris)
- Nathalie Yanze, Biosimilars Forum (Coherus)
- David Ceryak, PhRMA (Eli Lilly)
- Ryan Kaat, PhRMA
- Laura McKinley, PhRMA (Pfizer)
- Lucy Vereshchagina, PhRMA

Regulatory Science
FDA presented their proposal regarding BsUFA regulatory science. FDA highlighted the success of the GDUFA Regulatory Science Program and identified objectives for a proposed BsUFA regulatory science program specific to facilitating more efficient biosimilar and interchangeable product development and enhancing regulatory decision-making. FDA and Industry discussed aspects of the proposal, including opportunities for Industry engagement, program design, and resources. Industry agreed to discuss regulatory science internally and revisit in a future meeting.
Human Factors and URRA Timelines
FDA presented their proposal regarding timelines for reviewing Human Factors protocols and URRA. Industry asked clarifying questions about the proposal, which FDA responded to. FDA agreed to follow up with language clarification and details on the scope of URRA review. FDA and Industry discussed suggested resources to meet the proposed timelines.

Supplements and Labeling for Product Safety Updates
FDA presented their response to Industry's previously presented proposal regarding labeling for product safety updates. FDA and Industry discussed implications of the proposal, and Industry agreed to consider FDA’s proposal and present their response in a future meeting. FDA and Industry also discussed Industry’s follow-up questions regarding FDA’s supplement proposal presented on March 30th. FDA and Industry agreed to revisit supplement proposals in more detail the following week.

The goals for the next meeting on April 20th will be to revisit supplements, guidance development, and best practices for application review.

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