Stakeholder Consultation Meeting on MDUFA V Reauthorization
August 25, 2021, 1:00-1:30 PM
Virtual via Zoom

Purpose

To continue the process of FDA periodic consultation with representatives of stakeholder groups. Due to summer schedules, this meeting was shortened to a half hour and focused on sharing updates on the progress of the negotiations with industry.

Update on MDUFA V Negotiations

FDA welcomed stakeholders and expressed appreciation for stakeholders' participation and feedback used in the development of FDA's proposals. FDA provided an update on July and August meetings with Industry, including working group as well as negotiation meetings.

FDA provided additional detail on its proposals regarding Patient Science and Engagement (PSE), Device Safety, and the TPLC Advisory Program (TAP). FDA explained that the PSE proposal is a natural outgrowth of the work done during the MDUFA IV timeframe, incorporates feedback from a variety of stakeholders, and involves multiple components, including a patient engagement incubator, a patient science evidence accelerator, and a shared decision-making team. The Device Safety proposal includes enhancements to data access, data analysis, device safety evaluation, and risk communication. FDA clarified aspects of the TAP proposal, such as the objectives of the program, the role of the TAP advisors, and stakeholder participation.
FDA addressed questions and comments, mostly regarding the MDUFA V proposal on PSE. Due to the short duration of the meeting, FDA encouraged stakeholders to send additional questions and comments.

Attendees

Stakeholders

Ryne Carney, *Alliance for Aging Research*
Michael Ward, *Alliance for Aging Research*
Brandy Keys, *American Academy of Orthopedic Surgeons*
Will Schaffer, *American Academy of Orthopedic Surgeons*
Edward Hickey, *American Association of Kidney Patients*
Catherine Hill, *American Association of Neurological Surgeons / Congress of Neurological Surgeons*
Maria Gmitro, *Breast Implant Safety Alliance*
Marcia Howard, *Consumer Healthcare Products Association*
Dylan Simon, *EveryLife Foundation for Rare Diseases*
Amy Ohmer, *International Children's Advisory Network*
Leanne West, *International Children's Advisory Network*
Bennie Johnson, *Juvenile Diabetes Research Foundation International*
Andrew Sperling, *National Alliance on Mental Illness*
Thomas Eagen, *National Center for Health Research*
Diana Zuckerman, *National Center for Health Research*
Jennifer Dexter, *National Health Council*

Madris Kinard, *Patient Safety Action Network*
Cynthia Bens, *Personalized Medicine Coalition*
David Davenport, *Personalized Medicine Coalition*
Michael Abrams, *Public Citizen*

FDA Attendees

Lauren Roth, *OC OP, Lead Negotiator*
Cherron Blakely, *CDRH*
Kathryn Capanna, *CDRH*
Josh Chetta, *CDRH*
Misti Malone, *CDRH*
Elizabeth McNamara, *CDRH*
Malcolm Bertoni, *Consultant*
Cherie Ward-Peralta, *CBER*
Louise Howe, *OCC*
Darian Tarver, *OC OO*
Suzanne Schwartz, *CDRH*
Nia Benjamin, *CDRH*
Marta Gozzi, *CDRH*
Sharon Davis, *CDRH*
Brittany Caldwell, *CDRH*
Anindita Saha, *CDRH*
Christina Webber, *CDRH*
Mimi Nguyen, *CDRH*