Stakeholder Consultation Meeting on MDUFA V Reauthorization
October 27, 2021, 1:00-2:00 PM
Virtual via Zoom

Purpose

To continue the process of FDA periodic consultation with representatives of stakeholder groups. FDA focused this meeting on sharing the findings from the MDUFA IV Independent Assessment and providing updates on the progress of the negotiations with Industry.

MDUFA IV Independent Assessment

After welcoming the stakeholders, FDA summarized the MDUFA IV Independent Assessment of the Medical Device Review process which was published on September 30, 2021. The assessment included two phases. The first phase completed the evaluation of FDA's implementation of the recommendations from the MDUFA III independent assessment. The second phase was an extensive multi-year review that considered numerous areas including: Premarket Review Efficiencies; Infrastructure and FTE Allocations; Training and Alignment; Quality Management Program; Deficiencies; Pre-Submission Program; Third Party Review Program; Digital Health Program; Patient Science and Engagement Program; Real-World Evidence; and Special 510(k) Conversions.

FDA described key findings for each of these 11 areas and communicated that overall, the independent assessment found that for 10 of the 11 areas assessed, FDA met the commitments within the MDUFA IV Commitment Letter. The 11th area met all but one commitment (a digital health guidance document pending publication), which resulted in a recommendation. The independent assessment also identified six opportunities for FDA to support continuous improvement of the premarket program. FDA commented that this is a remarkable result, particularly when considering the unexpected pandemic-related work and the additional strain on Center resources from higher than projected non-COVID work.

Update on MDUFA V Negotiations

FDA provided a summary of the October 7, 2021 and October 20, 2021 negotiation meetings that were held with Industry since the last stakeholder consultation meeting.

Stakeholder Feedback

Stakeholders were given the opportunity to ask questions and provide comments. Stakeholders asked for more details regarding the ongoing conversation between FDA and Industry on the Patient Science and Engagement proposal. Stakeholders inquired about the balance of new FTE assignments between premarket and postmarket. Stakeholders asked about the negotiation timeline, the next steps in the reauthorization process, and how public stakeholders can provide input on the proposed recommendations. Finally, stakeholders expressed the concern that the recommendations that have been made have not been addressed in the negotiations. FDA provided answers and clarifications, including emphasizing that stakeholders' feedback is taken seriously and is factored into FDA's thinking related to MDUFA proposals. FDA additionally noted that, to the extent stakeholder recommendations are beyond the scope of the MDUFA

reauthorization, those recommendations are shared within CDRH and that FDA also welcomes such feedback through other opportunities for engagement with the Center.

Attendees

Stakeholders

Ryne Carney, *Alliance for Aging Research*
Brandy Keys, *American Academy of Orthopedic Surgeons*
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*
Paul Melmeyer, *Muscular Dystrophy Association*
Diana Zuckerman, *National Center for Health Research*
Thomas Eagen, *National Center for Health Research*
Jennifer Dexter, *National Health Council*
Madris Kinard, *Patient Safety Action Network*
Lisa McGiffert, *Patient Safety Action Network*
Cynthia Bens, *Personalized Medicine Coalition*
David Davenport, *Personalized Medicine Coalition*
Cara Tenenbaum, *Postpartum Pelvic Health Advocates*
Michael Abrams, *Public Citizen*
Linda Radach, *USA Patient Network, Patient Safety Action Network*

FDA Attendees

Lauren Roth, *OC OP, Lead Negotiator*
Cherron Blakely, *CDRH*
Kathryn Capanna, *CDRH*
Josh Chetta, *CDRH*
Misti Malone, *CDRH*
Malcolm Bertoni, *Consultant*
Cherie Ward-Peralta, *CBER*
Louise Howe, *OCC*
Jennifer Tomasello, *CDRH*
Michelle Tarver, *CDRH*
Nia Benjamin, *CDRH*
Marta Gozzi, *CDRH*
Ellen Olson, *CDRH*
Sharon Davis, *CDRH*
Mimi Nguyen, *CDRH*
Nancy Braier, *CDRH*