Stakeholder Consultation Meeting on MDUFA V Reauthorization
November 30, 2021, 1:00-2:00 PM
Virtual via Zoom

Purpose

To continue the process of FDA periodic consultation with representatives of stakeholder groups. During this meeting, FDA presented on the impact of increasing workload on MDUFA Commitments and provided updates on the progress of the negotiations with Industry.

Update on Impact of FDA's Increasing Workload on MDUFA Commitments

After welcoming participants, FDA shared highlights from the MDUFA IV Quarterly Performance Report, which was posted on November 16, 2021, and which reflects MDUFA IV actions through September 30, 2021.

FDA highlighted performance metrics for the review performance goals and shared outcome goals by submission type, noting that COVID-19 pandemic workload and CDRH's prioritization of that workload has impacted the Center's ability to meet MDUFA commitments. While FDA's performance was strong before the pandemic, the impact of COVID-19 on FDA's performance and predictability can now be seen in the performance data. In addition, CDRH continues to experience an increase in the number of conventional premarket submissions and the complexity of those submissions. For instance, in FY 2021, CDRH the highest volume of 510(k) submissions in recent years.

Update on MDUFA V Negotiations

FDA provided an update regarding two FDA-Industry negotiation meetings on November 9, 2021 and November 18, 2021, at which the parties had discussed potential commitments relating to international harmonization; enhanced management of user fee resources (e.g., hiring, vacancies, use of the carryover balance); 510(k) performance; and FDA's presentation of a revised MDUFA V package.

Stakeholder Feedback

FDA addressed stakeholders' questions, including questions around impact of submission trends on negotiations, transparency to the public, FDA's eSTAR program, and how funds in the carryover balance are considered in negotiations.

Attendees

Stakeholders:

Ryne Carney, *Alliance for Aging Research*
Brandy Keys, *American Academy of Orthopedic Surgeons*
Diana Clynes, *American Association of Kidney Patients*
Catherine Hill, *American Association of Neurological Surgeons / Congress of Neurological Surgeons*
Marcia Howard, *Consumer Healthcare Products Association*
Dylan Simon, *EveryLife Foundation for Rare Diseases*

Amy Ohmer, *International Children's Advisory Network*
Bennie Johnson, *Juvenile Diabetes Research Foundation International*
Paul Melmeyer, *Muscular Dystrophy Association*
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*
Michael Abrams, *Public Citizen*

FDA Attendees:

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