

**Stakeholder Consultation Meeting on MDUFA V Reauthorization**  
**February 28, 2022, 1:00-2:00 PM**  
**Virtual via Zoom**

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**Purpose**

To continue the process of FDA periodic consultation with representatives of stakeholder groups. During this meeting, FDA provided an update on the progress of the negotiations with Industry and presented additional data on FDA's increasing workload.

**Update on MDUFA V Negotiations and FDA's Increasing Workload**

FDA provided an update to stakeholders on the resumption of MDUFA negotiation meetings with Industry during the month of February. These included meetings on February 3 (regarding the process for continuing negotiations); February 8 (at which FDA presented data on 510(k) total time to decision; PMA total time to decision; and overall MDUFA workload trends); February 10 (at which the parties continued discussing MDUFA workload trends); February 15 (at which Industry presented a partial financial proposal for MDUFA V); February 17 work group meeting (regarding total time to decision and pre-submission metrics), and February 22 and 24 (at which FDA presented cost estimates and performance assumptions in support of a comprehensive MDUFA V framework).

FDA noted that, as it continued negotiations with Industry, the Agency continued to pursue the goals articulated at the start of the negotiation process: (1) enhance operational success, reduce device development times, and further accelerate patient access to high-quality, innovative, safe and effective devices; (2) optimize FDA infrastructure, staffing, and resources to keep pace with scientific development; and (3) improve device safety across the total product lifecycle.

FDA noted that it sought to achieve these goals within an environment in which the overall workload and the complexity of submissions are increasing. The Agency presented workload data that had been shared with Industry to illustrate these trends. FDA noted that the impact of pandemic-related work on MDUFA timelines was the subject of ongoing discussion with Industry, including the impact of FDA's policy regarding extended holds (i.e., > 180 days) on the shared outcome goals for 510(k) and PMA total time to decision.

FDA presented a summary of the proposed MDUFA V framework currently under discussion in Industry negotiations.

Stakeholder feedback included requests for additional information on the negotiations, for example regarding FDA's patient science and engagement proposal, as well as questions around complex 510(k) submissions, 510(k)-exempt devices, postmarket surveillance of Breakthrough Devices, and use of the carryover balance.

**Attendees:**

Stakeholders

- Michael Ward, *Alliance for Aging Research*
- Brandy Keys, *American Academy of Orthopedic Surgeons*
- Shreyasi Deb, *American Academy of Orthopaedic 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*
- Claire Destrampe, *International Children's Advisory Network*
- Bennie Johnson, *Juvenile Diabetes Research Foundation International*
- Paul Melmeyer, *Muscular Dystrophy Association*
- 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*
- 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

- Lauren Roth, *OC OP, Lead Negotiator*
- Kathryn Capanna, *CDRH*
- Misti Malone, *CDRH*
- Elizabeth McNamara, *CDRH*
- Michelle Tarver, *CDRH*
- Louise Howe, *OCC*
- Nia Benjamin, *CDRH*
- Marta Gozzi, *CDRH*
- Ellen Olson, *CDRH*
- Andrea Gray, *CBER*