

**Stakeholder Consultation Meeting on MDUFA V Reauthorization**  
**December 29, 2021, 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 presented on the impact of increasing workload on MDUFA Commitments and provided updates on the progress of the negotiations with industry.

**Update on MDUFA V Negotiations and MDUFA-related Activities**

FDA provided a summary of two FDA-Industry negotiation meetings on November 9, 2021 and November 18, 2021, which had previously been discussed at the November 30, 2021 stakeholder meeting.

FDA noted that current and projected workload had been a focus of negotiations with Industry, and FDA noted the recent publication of its FDA Voice blog post published on December 21, 2021. The post describes CDRH's efforts to manage a sustained increase in workload related to the pandemic and "conventional" premarket submissions. While CDRH's response to the pandemic remains a top priority, FDA anticipates a gradual transition back toward normal review timelines in 2022, but the ability to reach and sustain "normal" review times will depend on the course of the pandemic and adequate resources.

FDA also flagged recently published guidances and mechanisms for continued patient engagement with CDRH outside of the MDUFA reauthorization process.

FDA responded to stakeholders' questions regarding the TPLC Advisory Program to pilot enhanced early engagement on a subset of Breakthrough and STeP (Safer Technologies Program) designated products, the carryover balance, and hiring capabilities.

**Attendees**

Stakeholders:

Brandy Keys, *American Academy of Orthopedic Surgeons*  
Marcia Howard, *Consumer Healthcare Products Association*  
Nisha Quasabi, *EveryLife Foundation for Rare Diseases*  
Lisa McGiffert, *Patient Safety Action Network*  
Michael Abrams, *Public Citizen*  
Cara Tenenbaum, *Postpartum Pelvic Health Advocates*

FDA Attendees:

Lauren Roth, <i>OC OP, Lead Negotiator</i>	Louise Howe, <i>OCC</i>
Joshua Chetta, <i>CDRH</i>	Diane Goyette, <i>ORA</i>
Misti Malone, <i>CDRH</i>	Ellen Olson, <i>CDRH</i>
Elizabeth McNamara, <i>CDRH</i>	Sharon Davis, <i>CDRH</i>
Malcolm Bertoni, <i>Consultant</i>	Mimi Nguyen, <i>CDRH</i>
Cherie Ward-Peralta, <i>CBER</i>	