

**FDA – Industry MDUFA V Reauthorization Meeting**  
**March 3, 2022, 4:00 pm – 5:00 pm EST**  
**Virtual Via Zoom**

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**Purpose**

To discuss MDUFA V reauthorization.

**Attendees**

FDA

- Lauren Roth, *OC OP*
- Sara Aguel, *CDRH*
- Kathryn Capanna, *CDRH*
- Josh Chetta, *CDRH*
- Owen Faris, *CDRH*
- Misti Malone, *CDRH*
- Jonathan Sauer, *CDRH*
- Eli Tomar, *CDRH*
- Barbara Zimmerman, *CDRH*
- Cherie Ward-Peralta, *CBER*
- Claire Davies, *OCC*
- Malcolm Bertoni, *Consultant*
- Nia Benjamin, *CDRH*
- Ellen Olson, *CDRH*

Industry

*AdvaMed Team*

- Janet Trunzo, *AdvaMed*
- Phil Desjardins, *Johnson & Johnson*
- Danelle Miller, *Roche*
- Michael Pflieger, *Alcon*

*MITA Team*

- Peter Weems, *MITA*
- Nicole Zuk, *Siemens Healthineers*

*MDMA Team*

- Mark Leahey, *MDMA*
- John Manthei, *Latham & Watkins*
- Melanie Raska, *Boston Scientific*
- Elizabeth Sharp, *Cook Group*

*ACLA Team*

- Thomas Sparkman, *ACLA*
- Don Horton, *Labcorp*
- Shannon Bennet, *Mayo Clinic Laboratories*
- Amy Leiser, *Covington & Burling*

**Meeting Start Time:** 4:00 pm EST

**Executive Summary**

During the March 3, 2022 user fee negotiation meeting, FDA and Industry continued discussing aspects of the two proposals – one supported by AdvaMed and MITA, and one supported by MDMA and ACLA – with the goal of developing a consensus position.

**Discussion**

The parties discussed the options for designing a goal for pre-submissions, and FDA shared the importance to the Agency of providing adequate resources for the Agency to achieve the desired goal.

FDA shared concerns that the size of the TAP Pilot under the MDMA/ACLA proposal would not resource the pilot at a scale that would produce meaningful results. MDMA and ACLA shared

the perspective that their proposal provided flexibility for FDA to craft a meaningful pilot. FDA and Industry also continued to discuss ideas regarding the potential factors that the Agency could consider in selecting the Offices of Health Technology (OHTs) that would participate in the pilot and in ensuring a diversity of products would be eligible to participate in the pilot.

**Meeting End Time:** 5:00 pm EST