

FDA – Industry MDUFA V Reauthorization Meeting
March 2, 2022, 2:00 pm – 2:50 pm EST
Virtual Via Zoom

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*
- Louise Howe, *OCC*
- Malcolm Bertoni, *Consultant*
- Nia Benjamin, *CDRH*
- Marta Gozzi, *CDRH*
- Ellen Olson, *CDRH*

Industry

AdvaMed Team

- Janet Trunzo, *AdvaMed*
- Zach Rothstein, *AdvaMed*
- Nathan Brown, *Akin Group*
- Phil Desjardins, *Johnson & Johnson*
- Danelle Miller, *Roche*
- Michael Pfleger, *Alcon*
- Nicole Taylor Smith, *Medtronic*

MITA Team

- Peter Weems, *MITA*
- Diane Wurzburger, *GE Healthcare*

MDMA Team

- Mark Leahey, *MDMA*
- Melanie Raska, *Boston Scientific*

ACLA Team

- Thomas Sparkman, *ACLA*
- Don Horton, *Labcorp*
- Amy Leiser, *Covington & Burling*

Meeting Start Time: 2:00 pm EST

Executive Summary

During the March 2, 2022 user fee negotiation meeting, FDA and Industry continued to discuss the details of the framework that MDMA and ACLA presented on March 1, 2022. The parties addressed clarifying questions related to review performance goals, operating costs, size and scope of the TAP pilot, use of the carryover, and the inflation adjustment.

Meeting End Time: 2:50 pm EST