

**FDA – Industry MDUFA V Reauthorization Meeting**  
**February 3, 2022, 1:00 pm – 1:18 pm EST**  
**Virtual Via Zoom**

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**Purpose**

To discuss MDUFA V reauthorization.

**Attendees**

FDA

- Lauren Roth, *OC OP*
- Sara Aguel, *CDRH*
- Cherron Blakely, *CDRH*
- Kathryn Capanna, *CDRH*
- Josh Chetta, *CDRH*
- Misti Malone, *CDRH*
- Jonathan Sauers, *CDRH*
- Suzanne Schwartz, *CDRH*
- Don St. Pierre, *CDRH*
- Michelle Tarver, *CDRH*
- Eli Tomar, *CDRH*
- Barbara Zimmerman, *CDRH*
- Cherie Ward-Peralta, *CBER*
- Angela Granum, *CBER*
- Diane Goyette, *ORA*
- Claire Davies, *OCC*
- Louise Howe, *OCC*
- Malcolm Bertoni, *Consultant*
- Nia Benjamin, *CDRH*
- Sharon Davis, *CDRH*
- Marta Gozzi, *CDRH*
- Ellen Olson, *CDRH*

Industry

*AdvaMed Team*

- Janet Trunzo, *AdvaMed*
- Zach Rothstein, *AdvaMed*
- Nathan Brown, *Akin Gump*
- Phil Desjardins, *Johnson & Johnson*
- Michael Pflieger, *Alcon*
- Nicole Taylor Smith, *Medtronic*

*MITA Team*

- Peter Weems, *MITA*
- Diane Wurzbarger, *GE Healthcare*
- Nicole Zuk, *Siemens Healthineers*

*MDMA Team*

- Mark Leahey, *MDMA*
- Mark Gordon, *Alcon*
- Melanie Raska, *Boston Scientific*
- Elizabeth Sharp, *Cook Group*

*ACLA Team*

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

**Meeting Start Time:** 1:00 pm EST

**Executive Summary**

During the February 3, 2022 user fee negotiation meeting, FDA and Industry agreed to resume a regular cadence of negotiation meetings to reach agreement on a proposed MDUFA V commitment letter as quickly as possible. The parties scheduled future negotiation meetings for the following weeks.

**Meeting End Time:** 1:18 pm EST