FDA – Industry MDUFA V Reauthorization Meeting
February 24, 2022, 3:00 pm – 5:05 pm EST
Virtual Via Zoom

Purpose

To discuss MDUFA V reauthorization.

Attendees

FDA

- Lauren Roth, *OC OP*
- Sara Aguel, *CDRH*
- Cherron Blakely, *CDRH*
- Kathryn Capanna, *CDRH*
- Josh Chetta, *CDRH*
- Owen Faris, *CDRH*
- Misti Malone, *CDRH*
- Jonathan Sauer, *CDRH*
- Don St. Pierre, *CDRH*
- Michelle Tarver, *CDRH*
- Eli Tomar, *CDRH*
- Barbara Zimmerman, *CDRH*
- Cherie Ward-Peralta, *CBER*
- Angela Granum, *CBER*
- Claire Davies, *OCC*
- Louise Howe, *OCC*
- Emily Galloway, *OC Econ*
- Malcolm Bertoni, *Consultant*
- Nia Benjamin, *CDRH*
- Marta Gozzi, *CDRH*
- Ellen Olson, *CDRH*

Industry

AdvaMed Team

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

MITA Team

- Peter Weems, *MITA*
- Diane Wurzburger, *GE Healthcare*
- Elisabeth George, *Philips*
- Nicole Zuk, *Siemens Healthineers*

MDMA Team

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

ACLA Team

- Don Horton, *Labcorp*
- Shannon Bennett, *Mayo Clinic Laboratories*
- Amy Leiser, *Covington & Burling*

Meeting Start Time: 3:00 pm EST

Executive Summary

During the February 24, 2022 user fee negotiation meeting, FDA and Industry continued to discuss the details of the financial and performance goals framework that was supported by two trade associations, AdvaMed and MITA.

Discussion

FDA and Industry discussed the proposed ceiling on the carryover balance, as well as how FDA and Industry could work together during MDUFA V to seek alignment on how best to use carryover balance funds.

Regarding hiring accountability, FDA and Industry discussed how hires would be defined and tracked for purposes of determining whether the annual targets were met. FDA and Industry also further discussed the operational aspects of hiring, since FDA's cost estimates included application of the quarterly on-boarding assumption. In addition, FDA clarified its expectation that the independent assessment of workforce metrics would include evaluating methodologies to define a MDUFA-funded position for purposes, in the future, of being able to determine a vacancy rate for those positions.

FDA and representatives for ACLA discussed the extent to which MDUFA V cost estimates included submissions for laboratory developed tests (LDTs). FDA indicated that cost estimates presented did not include a significant increase in LDT submissions. FDA also noted the MDUFA IV agreement included language relating to LDTs that the Agency would be willing to retain for MDUFA V (i.e., that the Agency "commits to treat LDTs no less favorably than other devices to which MDUFA performance goals apply"). ACLA noted that it continued to support the proposal that Industry presented on February 15th, but it would assess the additional information that had been discussed during the February 22nd and 24th meetings.

FDA and Industry further discussed the options for establishing a 510(k) total time to decision goal. The parties also further discussed the launch of the TAP Pilot, including the potential factors that the Agency could consider in selecting the Offices of Health Technology (OHTs) that would participate in the pilot and in defining the scope of products that would be eligible to participate in the pilot. Industry signaled that they would review the additional details that had been discussed during the February 22nd and February 24th meetings.

Meeting End Time: 5:05 pm EST