FDA – Industry MDUFA V Reauthorization Meeting
February 15, 2022, 3:00 pm – 4:30 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*
- Nathan Brown, *Akin Gump*
- Phil Desjardins, *Johnson & Johnson*
- Danelle Miller, *Roche*
- Michael Pfleger, *Alcon*
- Nicole Taylor Smith, *Medtronic*

MITA Team

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

MDMA Team

- Mark Leahey, *MDMA*
- John Manthei, *Lathan & Watkins*
- Melanie Raska, *Boston Scientific*

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 15, 2022 user fee negotiation meeting, Industry presented a proposal that included a total of $1.72 billion in fees during MDUFA V and a variety of performance improvements and other program features. After asking clarifying questions, FDA conveyed that the Agency could not accept the proposal because the resources were not sufficient to achieve the proposed performance commitments.

Industry's February 15 Proposal

Industry presented its proposal and identified areas that they considered unresolved, requiring additional discussion.

Base Funding

- Total fees (not inclusive of carryover balance) of $1.72 billion over 5 years of MDUFA V, expressed in FY 2021 dollars.
    - FY 2023 total fees would be "locked in" by assuming annual cap on inflation adjustment of 2% from FY 2021 to FY 2023, resulting in a 5-year total of $1.818 billion in FY 2023 dollars, before further inflation adjustments after FY 2023.
- Funding would be mapped to FTEs and programs.
- Use of MDUFA IV carryover balance to be discussed, including some pre-hires in FY 2022.

Appropriations Trigger

- Increased to $408M (based on FY 2021 appropriation) or 95% of FY 2022 appropriation, whichever is higher.

Carryover Balances

- Capped at $60 million.
- Funds exceeding the cap credited next year by reducing facility registration fees.
- Alignment between FDA and Industry for use of any available carryover funds.

Hiring Targets

- Establish annual hiring targets for FY 2023 through FY 2027
- If 90% of hiring target not achieved, then unused funds would be credited the following year by reducing facility registration fees.

Vacancy Rates

- Conduct an assessment of human resources to determine average vacancy rates for MDUFA-funded hires.
- Issue a report by June 30, 2024 that provides definitions for MDUFA-funded hires and FTE parameters, and a foundation for future vacancy rates.
- Establish a mechanism to track all MDUFA-funded hires from MDUFA I through V.

Performance Goals

- AI Letters / basis for deficiency: FY23: 75%, FY24: 80%, FY25: 85%, FY26: 90%, FY27: 95%.
- 510(k) Total Time to Decision (TTD) goal: 108 days (Industry understands current public health emergency may impact FDA's ability to meet goal in FY23-24).
- PMA TTD goal: FY23: 290 days, FY24: 285, FY25: 280, FY26: 275, FY27: 270 days (Industry understands current public health emergency may impact FDA's ability to meet goal in FY23-24).
- De Novo decision in 150 days: FY23: 70%, FY24: 75%, FY25: 80%, FY26: 85%, FY27: 90%.
    - Update de Novo guidance to improve acceptance rate and review process.

- Pre-submission written feedback in 70 days: FY23: 85%, FY24: 90%, FY25-27: 95%.
    - Revise guidance by 12/31/23 to address when informal interaction versus pre-sub is warranted, allowing multiple issues in a single meeting, and appropriate use of pre-subs.
- All other FDA decision goals and ongoing commitments for MDUFA IV apply to MDUFA V.

One-Time Costs

- Same as Industry's October 2021 proposal, addressing within the base funding:
    - Patient Science and Engagement
    - Standards
    - International Harmonization
    - Real World Evidence
    - Third Party Review
    - Recruitment and retention
    - Independent Assessments

Industry Association Comments

After the presentation of Industry's proposal framework, each Industry association provided additional comments.

AdvaMed stated that their position is that the MDUFA V package should include the concept of performance-based triggers with the opportunity for add-on payments, and they would like to discuss further how those could be structured.

MITA stated that they supported the concept of performance-based triggers with add-on payments and looked forward to exploring how to structure them.

MDMA stated that Industry's proposal represents a substantial increase in funding for FDA and substantial movement by Industry toward FDA's position over the course of the negotiations, and MDMA shares the desire to reach an agreement expeditiously. MDMA acknowledged that Industry's October proposal included performance-based triggers with add-on payments, and that MDMA is open to discussing the idea if FDA is willing to propose enhanced performance goals that exceed pre-COVID performance levels.

ACLA stated that while today's Industry proposal doesn't include performance-based triggers with add-on payments, ACLA is willing to consider in good faith any counter proposal that might include that feature.

FDA Questions

After the conclusion of Industry's remarks, FDA engaged Industry with some clarifying questions.

FDA asked about Industry's assumptions and rationale for the 2% annual inflation adjustment cap going from FY21 dollars to FY23 dollars, given that MDUFA currently has a 4% annual cap on the base inflation adjustment. Industry responded that they wanted greater certainty about what the fees would be in FY23.

FDA asked about how they arrived at the $60 million cap on the carryover balance. Industry responded that they multiplied the current 1 month statutory reserve amount by 3 and rounded up to get a 3-month operating reserve based on the current size of the program.

FDA noted that Industry's proposal did not include anything about the Total Product Life Cycle Advisory Program (TAP) pilot, and asked if that was discussed. AdvaMed responded that it was their expectation that the package would include a TAP pilot. MITA noted that there were many details that needed to be figured out.

FDA asked about the assumptions underlying Industry's proposed pre-sub goals, particularly given FDA's concern about the rapid growth in submission volume. Industry responded that their proposal is partly based on pre-COVID performance, as well as a belief that submission volume will level off if there is an effort to clarify the intent and improve the process through revised guidance.

FDA asked for clarification about the proposed commitment to update the De Novo guidance to "improve acceptance rate and review process." Industry responded that they believe the program can be streamlined, particularly if Industry can better understand why the acceptance rate is not higher. FDA noted that they recently made available a new eSTAR template for De Novos, which should clarify FDA requirements and increase acceptance rates.

FDA Response to Industry's February 15 Proposal

FDA provided its response to Industry's proposal. FDA expressed its appreciation for the opportunity to get answers to its questions, and had no further questions for today. FDA stated it could not accept Industry's proposal because, in FDA's view, it would not set up the program for success. FDA subject matter experts stated that their many years of experience managing the MDUFA program have demonstrated their ability to predict performance accurately, and that industry's proposed framework is not feasible.

FDA also asked for clarification about whether today's proposal was a complete consensus among all Industry associations. AdvaMed stated that today's proposal was incomplete from their perspective because it did not include the performance-based triggers with add-on payments. MDMA stated that from their perspective, it was a complete proposal, though they are open to considering additional components.

Meeting End Time: 4:30 pm EST