FDA – Industry MDUFA V Reauthorization Meeting
March 7, 2022, 2:00 pm – 2:30 pm EST and 8:00 – 8:30 pm EST
Virtual Via Zoom

Purpose

To discuss MDUFA V reauthorization.

Attendees (2:00 – 2:30 pm)

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*

MITA Team

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

MDMA Team

- Mark Leahey, *MDMA*

ACLA Team

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

Initial Meeting Time: 2:00-2:30 pm EST

Attendees (8:00 – 8:30 pm)

FDA

- Lauren Roth*, OC OP*
- Misti Malone*, CDRH*
- Barbara Zimmerman*, CDRH*
- Malcolm Bertoni*, Consultant*

Industry

- Janet Trunzo, AdvaMed
- Zach Rothstein, AdvaMed
- Peter Weems, MITA
- Mark Leahey, MDMA
- Thomas Sparkman, ACLA

Second Meeting Time: 8:00-8:30 pm EST

Executive Summary

FDA and Industry convened for two user fee negotiation meetings on March 7th. During the first meeting, FDA and Industry discussed the Industry consensus proposal and the FDA response

that had been exchanged in writing the day before. During the second meeting, FDA and Industry agreed in principle to the framework presented in the FDA response.

Industry Proposal

The Industry proposal reflected the following key changes to cost estimates and performance goals. Industry proposed that user fee revenues would provide for a five-year total of $1.751 billion, with the opportunity for add-on payments of $80 million. In addition, Industry proposed that FDA invest $112 million from the MDUFA IV carryover to fund the TAP Pilot.

The proposal contemplated that add-on payments would be available if performance goals were met in the following areas: Pre-submissions; De Novo requests; 510(k) submissions; and PMA submissions.

Pre-submissions: The Pre-submission proposal reflected the following conditions:

- To help bridge the divide between FDA and Industry Pre-submission growth projections, the goal structure would reflect both a "high volume" and "low volume" goal for FY23-24.
    - For FY23, the high-volume goal would be 75% of up to 4,300 Pre-submissions if 3,585 or more Pre-submissions were received; the low volume goal would be 90% if fewer than 3,585 Pre-submissions were received that year.
    - For FY24, the high-volume goal would be 85% of up to 4,300 submissions if 4,060 or more Pre-submissions were received; the low volume goal would be 90% if fewer than 4,060 Pre-submissions were received.
    - For FY25-27, the goal would be 90% of up to 4,300 submissions, unless an add-on payment was applied.
- During any years in which Pre-submission add-on payments are applied (e.g., FY25-27), the Pre-submission goal would be 90% of up to 4,700 Pre-submissions.
- Unlike the prior proposals, there would not be a cap on receipt of Pre-submissions; rather, if the Pre-submission would take longer than the goal timeline, the reviewer would communicate with the submitter about when feedback would be received.

De Novo requests: The proposal related to the De Novo decision day goal mirrored the proposal discussed on February 22nd and 24th.

510(k) submissions:

- For guaranteed base funding:
    - The TTD goal would be: FY23: 128 days; FY24: 124 days; FY25-27: 112 days; and,
    - The FDA decision day goal would be that FDA will issue a MDUFA decision for 95% of 510(k) submissions within 90 days.
- If the 510(k) goals were to be achieved for FY23, then add-on payments would be applied in FY26 and the 510(k) TTD goal would be set to 108 days. If the 510(k)

goals were to be achieved in FY24, then add-on payments would be applied in FY27 and the 510(k) TTD goal would be set to 108 days.
- 510(k) submissions with extended holds (i.e., > 180-days), if any, would be excluded from the cohort. For FY23, a 5% trim would be applied to the top of the cohort. For FY24-27, the standard 2% trim would be applied to the top and bottom of the cohort.

PMA submissions: The proposal related to the PMA decision day goal and TTD goal mirrored the proposal discussed on February 22nd and 24th.

FDA Response

The FDA response reflected the following key changes to cost estimates and performance goals. FDA proposed that user fee revenues would provide for a five-year total of $1.784 billion, with the opportunity for add-on payments of approximately $115 million. In addition, FDA proposed that at least $118 million be invested from the MDUFA IV carryover balance, including $110 million to fund the TAP Pilot and $8 million to maintain the Third Party Review Program.

Pre-submissions: FDA included a Pre-submission proposal that adopted the construct of high- and low-volume goals and, in the Agency's view, would adequately resource the Pre-submission program with assurances for both Industry and FDA—on the low-volume end, to ensure value to Industry for the funding; on the high-end, to protect FDA against increases in Pre-submission volume that would not be resourced by the funding. Specifically, FDA proposed that:

- During the years in which add-on payments are not applied, the Pre-submission goal would be capped at 4,300 submissions, except for Pre-submissions associated with Breakthrough-designated or STeP products.
- If add-on payments were to be applied in FY25-26, the Pre-submission goal would be capped at 4,700 or 4,800 submissions respectively, except for Pre-submissions associated with Breakthrough-designated or STeP products.
- If add-on payments were to be applied in FY27, the Pre-submission goal would be 90%, with no cap.
- Any Pre-submissions other than those for Breakthrough-designated and STeP products above the cap would receive feedback as resources permit.
- In all years, for any Pre-submissions under the cap for which FDA does not meet the written feedback goal, FDA would communicate with the sponsor about a timeline for providing written feedback.

Operating costs: To ensure the stability of the program payroll and improve FDA's ability to hire and retain top talent, FDA's response restored the portions of operating costs for the Pre-submissions and back-to-basics/fill MDUFA gaps estimates that had been reduced in Industry's proposal.

TAP Pilot: While reflecting a substantial decrease in TAP Pilot funding, FDA's response proposed to resource the pilot at what FDA had judged was a meaningful level throughout MDUFA V, using a mixture of carryover balance funds (in FY23-26) and user fee revenue (in FY27).

Second Meeting

During the follow-up meeting, FDA and Industry agreed in principle to the framework reflected in FDA's response, contingent on mutual agreement to the Commitment Letter. The parties established a schedule for daily work group meetings to resolve the details of the Commitment Letter.