FDA – Industry MDUFA V Reauthorization Meeting
March 17, 2021, 1:15 pm – 4:45 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*
- Rhonda Corbin, *CDRH*
- Owen Faris, *CDRH*
- Elizabeth Hillebrenner, *CDRH*
- Misti Malone, *CDRH*
- Don St. Pierre, *CDRH*
- Michelle Tarver, *CDRH*
- Barbara Zimmerman, *CDRH*
- Malcolm Bertoni, *Consultant*
- Cherie Ward-Peralta, *CBER*
- Jan Welch, *ORA*
- Claire Davies, *OCC*
- Louise Howe, *OCC*
- Darian Tarver, *OC OO*
- Emily Galloway, *OC Econ*
- Nia Benjamin, *CDRH*
- Marta Gozzi, *CDRH*
- Ellen Olson, *CDRH*
- Sharon Davis, *CDRH*
- Sonja Fulmer, *CDRH*

Industry

AdvaMed Team

- Janet Trunzo, *AdvaMed*
- Zach Rothstein, *AdvaMed*
- Nathan Brown, *Akin Gump*
- Phil Desjardins, *Johnson & Johnson*
- Michael Pfleger, *Alcon*
- Danelle Miller, *Roche*
- 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*
- John Manthei, *Latham & Watkins*
- Mark Gordon, *Alcon*
- Melanie Raska, *Boston Scientific*
- Elizabeth Sharp, *Cook Group*

ACLA Team

- Thomas Sparkman, *ACLA*
- Don Horton, *Labcorp*
- Shannon Bennett, *Mayo Clinic Laboratories*

Meeting Start Time: 1:15 pm EST

Executive Summary

At the second user fee negotiation meeting, FDA and Industry discussed external stakeholder feedback on MDUFA reauthorization; MDUFA IV performance; a high-level summary of MDUFA IV financial information; digital transformation; FDA's methodology for calculating

average cost per full time equivalent (FTE); and an update on FDA's recruitment and retention efforts for positions funded by MDUFA IV.

Presentation of Stakeholder Feedback

FDA summarized stakeholder feedback from the public meeting on October 27, 2020, written comments received to the public docket, and input provided by stakeholders during the consultation meeting held on March 10, 2021. This feedback reflected perspectives offered by patient and consumer advocacy groups, healthcare professionals, scientific and academic experts, trade associations, and companies. Stakeholder topics of interest included enhanced engagement with industry, patients, and physician society stakeholders; expanded payor engagement; increased transparency and continued use of real-world evidence to support regulatory decision making across the total product lifecycle; increased investments in digital health; increased diversity in clinical trials and patient engagement activities; incentivized innovation for underserved populations; and device safety, such as through enhanced postmarket surveillance and improved FDA communications to reduce potential confusion among healthcare professionals and patients.

FDA Perspective on MDUFA IV Performance

FDA revisited the discussion of MDUFA IV performance that had occurred during the February 24th meeting, noting that it disagreed with industry's characterization of aspects of FDA's MDUFA IV performance as "not being met or unlikely to be met."

Specifically, FDA noted that the total time to decision goal for 510(k) submissions is a shared outcome goal and requested that industry provide information at the April 7th meeting about actions that industry has taken to advance this goal during MDUFA IV. Regarding pre-submissions, FDA noted that it is too early to predict performance of the goal for FY 2021. Regarding digital health, FDA disagreed with the characterization of missing more than one digital health commitment and expressed its willingness to discuss new digital health commitments as part of MDUFA V; however, Industry maintained its disagreement.

Regarding deficiency letters, FDA expressed its view that the Agency had met the MDUFA IV commitments by publishing an update to existing guidance, providing training to staff and managers, and completing an audit by FY2020. Industry disagreed with FDA's view that the Deficiency Letter commitments had been met. Points of disagreement included interpretation of the MDUFA IV Commitment Letter. Industry interpreted the Commitment Letter as reflecting a commitment that all deficiency letters would include a statement for the basis of the deficiency, and stated that FDA had missed this goal. FDA explained that it does not view the Deficiency Letter provision as a commitment to 100%, but rather, an aspirational goal of 100%, towards which it is diligently working and expecting to see improvements. FDA noted they would need more resources for this to be an actionable goal of 100% compliance. Industry noted that they appreciate FDA's efforts in this area, but maintained their disagreement. In addition, Industry pointed to results from CDRH's quality management audit related to deficiency letters, stating that the results showed CDRH was providing a basis for deficiencies nowhere near 100% of the time (25% in FY 19 and 50% in FY 20), and the provision of funding for additional supervisory positions was specifically to ensure review of deficiency letters for compliance with this objective. FDA noted that the audit reflected a higher standard than the commitment letter.

Finally, Industry said that it is critical for FDA to provide justification for the deficiencies so industry can clearly understand the requirements and avoid future deficiencies. FDA questioned whether a focus on citations in deficiency letters could be distracting from a possible mutual goal of promoting high-quality premarket submissions that do not necessitate the need for any deficiency letters to be issued. FDA and Industry agreed that it would be useful to continue discussing this topic at a future negotiation meeting.

MDUFA IV Financial Information

FDA provided high-level MDUFA IV financial information. FDA shared an overview of total user fee target revenue across FDA user fee programs and noted that, while the MDUFA IV agreement provided a meaningful increase in funds for the MDUFA program, the combined total of user fees that contribute to the human drugs program is more than seven times higher—i.e., that the total target user fee revenue, adjusted for inflation, is approximately $ 1,096,450,000 for MDUFA IV and approximately $ 8,046,363,000 for PDUFA VI, GDUFA II, and BsUFA II combined. Industry objected that this was not an appropriate comparison, and Industry discussed with FDA the differences between the drug and device industries that they believe are relevant to the different levels of funding. For instance, Industry noted the dramatic differences between the drug and device industry, including the fact that many drugs have annual revenues in the billions of dollars and market sizes ten times greater than a single medical device product. Industry also noted the countervailing concerns about "agency capture", when industry is the primary funder of FDA, that have been raised by stakeholders. By way of comparison, FDA noted that, even isolating the comparison to the generic drug user fee agreement, the total target user fee revenue, adjusted for inflation, was more than double the amount provided for the medical device program. Further, FDA noted, the stark contrast between the level of funding for the drug and device programs has raised external questions of what more FDA could achieve with the medical device program if it was resourced at levels comparable to the drugs programs.

FDA also provided financial data through the end of FY 2020 on MDUFA user fee revenue by source; MDUFA process spending; percentage of total program spending by agency component; and the MDUFA carryover balance available for use of over $200 million. FDA stated there is also an additional $89 million in carryover balance unavailable for use. FDA and Industry discussed the potential use of funds included in the carryover balance. FDA explained that the carryover balance includes funds that FDA plans to allocate for acquisition, maintenance, and updates of IT resources through its Digital Transformation Initiative. Although FDA indicated that it had previously discussed this with industry members and how the funds were obtained to support implementation of the Digital Transformation Initiative, industry participants at the meeting indicated that they had not been previously informed regarding FDA's view of how funds from the carryover balance should be used. Industry expressed concern about the existence of significant carryover balances at a time when MDUFA submissions are being delayed due to FDA's focus on responding to the COVID-19 pandemic. Industry also stated that although MDUFA funding for IT had previously been agreed to and negotiated, this did not extend to all aspects of the Digital Transformation Initiative. Industry requested additional information, including clarification on the source of the carryover balance, whether the funds had accumulated due to lack of hiring, and when FDA had decided to pursue the Digital Transformation Initiative. Industry noted that under MDUFA II and III the offset in MDUFA operated to apply any carryover balance to offset the fees in the fifth year. Industry stated that the

use of any carryover funds should be targeted to areas of mutual interest under MDUFA IV to enhance premarket activities. FDA and Industry agreed that discussion of this topic should continue at a future negotiation meeting.

FDA's Overview of Digital Transformation

FDA described the current IT infrastructure as outdated, fragmented, and inefficient. FDA noted that the aging IT system has been slowing the regulatory process. MDUFA IV included commitments regarding IT infrastructure for submission management, including electronic submission templates and linking pre-submission with subsequent premarket submissions. However, FDA explained that digital transformation will go beyond these specific MDUFA IV commitments to improve transparency, reduce duplicative efforts, create an integrated environment and ensure integrity of data. The first feature of the Customer Collaborative Portal, the Premarket Progress Tracker intended to support process transparency and communication with submitters, was released as a soft launch on March 8, 2021, with a goal of having about 100 participants.

Fully-Loaded FTE Cost Model Methodology

FDA was joined by subject matter experts from the Office of Finance, Budget, Acquisitions, and Planning (OFBAP) to provide an overview of the Agency's methodology for calculating the cost per FTE. FDA explained that the cost per FTE is calculated by dividing total included costs by official FTE counts, and that the costs consist of three components—(1) personnel compensation and benefits costs (PC&B); (2) certain non-pay costs; and (3) rent. For pay costs, the methodology reflects a Center-specific summation of all PC&B costs, divided by Center-specific FTEs. For example, in FY 2020, CDRH's average pay cost per FTE was approximately $183,000. FDA noted the average pay cost will be impacted by CURES Act pay authorities that allow FDA to provide higher salaries for specific positions and skills. Industry asked for clarification on included versus excluded non-pay costs and stated its view that FTE costs should be more accurate to the specific user fee agreement. Industry also inquired about rent costs, CURES pay, FTE costs for PDUFA, and how additional one-time costs (such as IT expenditures or congressional appropriations for a specific program) would affect the average cost per FTE methodology. FDA expressed an openness to looking into whether non-pay costs could be isolated to the four FDA components that participate in the MDUFA program—CDRH, CBER, ORA, and headquarters and a willingness to continue the dialogue at a future negotiation meeting.

Industry Perspective on Reauthorization

Industry stated its objectives and principles for MDUFA V, including: (1) Timely patient access to safe and effective products, (2) Identify mutual goals and process improvements to achieve timely patient access, (3) Congressional appropriations should remain the primary source of CDRH's funding; user fees are additive, (4) Use of fees solely for premarket review process, and (5) Industry has made significant and material investments under MDUFA I-IV.

Industry discussed its position that a complete and accurate accounting of MDUFA costs is necessary and in the interest of all parties, including FDA, industry, and the public. Industry said, given that FTEs are a major driver of total MDUFA costs, they requested additional detail to

determine an accurate cost per FTE. Industry requested additional information on how many MDUFA I-III positions remain vacant, FDA's plans for filling MDUFA IV FTEs that remain vacant, and why the number of "device review process" FTEs dropped between FY18 and FY19.

Industry stated its view that the MDUFA fees should be used to fund reviewers. Industry expressed interest in further discussing how to use carryover funds.

FDA's overview on Recruitment and Retention

In response to industry's request during the first negotiation meeting that FDA provide more information about hiring for MDUFA IV positions, FDA explained that the Agency faced a number of hiring challenges during FY 2018 and FY 2019. FDA outlined efforts that have been undertaken to address those challenges, which resulted in FY 2020 being a successful hiring year. FDA noted that 92% of new MDUFA IV positions had been filled through the end of FY 2020, with 15 of 189 unfilled. In addition, FDA noted that 14 positions were vacant due to attrition, which reflected a roughly 7% attrition rate. FDA stated that it expects to meet its MDUFA IV hiring targets in FY 2021. Industry requested additional information regarding how user fee funds contributed to recruitment efforts and how FDA counts MDUFA IV positions as having been filled. FDA agreed to provide additional detail at a future meeting.

Next Meeting

The next meeting is scheduled on April 7, 2021.

Meeting End Time: 4:43 pm EST