

FDA – Industry MDUFA V Reauthorization Meeting
June 30, 2021, 12:30 pm – 4:00 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 Sauers, *CDRH*
- Suzanne Schwartz, *CDRH*
- Don St. Pierre, *CDRH*
- Michelle Tarver, *CDRH*
- Barbara Zimmerman, *CDRH*
- Cherie Ward-Peralta, *CBER*
- Diane Goyette, *ORA*
- Jan Welch, *ORA*
- Claire Davies, *OCC*
- Louise Howe, *OCC*
- Darian Tarver, *OC OO*
- Emily Galloway, *OC Econ*
- Malcolm Bertoni, *Consultant*
- Nia Benjamin, *CDRH*
- Sharon Davis, *CDRH*
- Marta Gozzi, *CDRH*
- Ellen Olson, *CDRH*
- Hanah Pham, *CDRH*
- Mimi Nguyen, *CDRH*

Industry

AdvaMed Team

- Janet Trunzo, *AdvaMed*
- Zach Rothstein, *AdvaMed*
- Nathan Brown, *Akin Gump*
- Phil Desjardins, *Johnson & Johnson*
- Michael Pflieger, *Alcon*
- Danelle Miller, *Roche*
- 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 Laboratories*

Meeting Start Time: 12:30 pm EST

Executive Summary

During the June 30, 2021 user fee negotiation meeting, FDA presented additional information in response to Industry’s financial questions related to full time equivalents (FTEs) and position management, the fully-loaded FTE cost model, and the carryover balance. Industry reiterated their principles and proposals for MDUFA V.

FDA Presentation

Given Industry's interest in having a better understanding of the financial operation of the MDUFA program, FDA used this negotiation meeting to provide background information regarding the concept of a "full-time equivalent" (FTE); challenges with identifying "MDUFA-funded" positions or vacancies; the Agency's methodology for calculating the cost per FTE; factors contributing to the size of the carryover balance; and information regarding COVID-19 supplemental funding that is allocated for medical device premarket review work.

Full time equivalents (FTEs), Positions, Vacancies, and a Proposal to Retain an Independent Contractor During MDUFA V

FDA explained that a full-time equivalent (FTE) is a calculation that reflects the total number of regular straight-time hours worked by employees, divided by the number of compensable hours applicable to each fiscal year and does not include overtime or holiday hours. A process FTE is a mechanism for tracking the number of labor hours expended on specific work activities as captured from employee time reporting.

An FTE is not equal to a position, and positions are not specified as being funded from a specific resource. For example, the responsibilities of a position may include both MDUFA and non-MDUFA work. Time reporting data is used to calculate the percentage of time that FDA employees work on MDUFA activities. The actual number of hours worked (excluding overtime) is converted to an estimate of MDUFA process FTEs (i.e., the equivalent number of people needed to perform MDUFA process work). Through this model, user fees fund a portion of MDUFA process work, not specific positions or vacancies. In response to Industry's questions, FDA explained that this is not a new process, although the nomenclature of "FTEs" and "new hires" can become confusing. FDA also noted that it uses this methodology to project estimated resource needs as part of user fee negotiations.

In response to Industry's question about operations during a shutdown, FDA explained that specific positions are not "tagged" as MDUFA process, but instead, the individuals who will continue to do MDUFA-funded work during a shutdown are determined based on the process-related work. Industry requested additional details on the numbers of staff and managers, the conversion factor for FTE estimates, and the number of vacancies.

Regarding vacancies, FDA explained that the total numbers of positions and vacancies are not static from year to year; rather, they depend on (1) available resources and (2) program needs. As discussed during the June 16th negotiation meeting, CDRH does not have "user fee funded vacancies." However, as part of MDUFA IV, FDA received funding for 217 new FTEs. To enable tracking of our progress hiring new staff, FDA implemented a position management system and designated 217 positions as "MDUFA IV hires." Through June 19, 2021, 206 of 217 (95%) of the MDUFA IV hires had been filled.

In addition, FDA addressed Industry's question from the June 16th meeting about how the Agency calculated vacancies in response to a media inquiry in 2016. FDA explained that it had simply been an approximation based on the number of positions for which CDRH was actively recruiting Center-wide at the time, with an estimate of MDUFA process percentages applied.

FDA explained that this back-of-the-envelope methodology isn't useful to estimating MDUFA program resource needs because it was not based on the actual nature of the positions for which CDRH was recruiting and it was calculated prior to the Center's reorganization in 2019 (so would not be an apples-to-apples comparison). However, to help try to address Industry's question about vacancies, FDA noted that, as of June 28, 2021, CDRH was actively recruiting for 196 total vacancies, a number not specific to the MDUFA program. This vacancy number included 97 candidates who had been selected, of which 29 candidates had confirmed start dates.

FDA noted that other FDA Centers have different position management capabilities. For instance, as part of PDUFA VI, CDER committed to complete development and implementation of a position management baseline accounting of all current positions and FTE counts for each applicable Center and office, including filled and vacant positions; a governance structure for on-going position management accountable to senior management; and a position management policy and guidance ratified by senior management. To support answering these questions regarding FTE and position management, FDA proposed that MDUFA V provide funding for the Agency to engage a qualified, independent contractor with expertise in assessing human resources operations to evaluate and make recommendations, as needed, regarding CDRH's current system for tracking hiring and staff capacity for the MDUFA program. Reporting by the contractor could provide transparency to industry and the public.

Fully-loaded FTE Cost Model

FDA described the components of the fully-loaded FTE cost model: (1) personnel compensation and benefits (PC&B); (2) non-pay costs, including non-pay costs and working capital fund costs; and (3) rent. As an example, FDA provided details about the breakdown from the current FY2023 fully-loaded cost model, which estimates an average total of \$307,022 per FTE, including an average \$180,000 in PC&B costs; \$68,200 in non-pay costs; \$34,878 in working capital fund costs; and \$23,944 in rent.

FDA clarified that the non-pay component includes recurring costs specific to MDUFA process whereas the working capital fund and rent are determined Agency-wide. In response to Industry's proposal that a cost per FTE of \$225,000 is reasonable, FDA explained that the cost model methodology is based on actual costs, so it more accurately reflects the true cost of FTEs. However, FDA noted two aspects of the model that could be further refined as part of MDUFA V negotiations.

First, FDA explained that the current version of the cost model calculates the average non-pay costs based on relevant operating costs that are incurred Agency-wide (excluding the Center for Tobacco Products). Instead, as part of the MDUFA V methodology, FDA proposed to calculate the average non-pay costs based on relevant operating costs only from the FDA components that participate in the MDUFA program. This change would result in a savings of \$7,693 per FTE.

Second, FDA noted that MDUFA V must address rising pay costs. A limitation of the PC&B component of the fully-loaded cost model is that it's based on actual pay costs from an earlier year. For instance, the PC&B component of the FY 2023 model is based on payroll actuals from FY 2019 for the four FDA components that participate in the MDUFA program. Under the model, the weighted average payroll cost for FY 2023 is estimated to be \$180,000. However,

FDA estimates that CDRH's average payroll costs for FY 2022 will have already exceeded that amount and will be closer to \$191,000 per year. FDA asserted that its ability to pay higher salaries is critical to the Agency's ability to recruit and retain outstanding, highly qualified individuals to scientific, technical, and professional positions that support the development, review, and regulation of medical products. Accordingly, addressing rising payroll costs will be critical to the success of MDUFA V.

MDUFA Carryover Balance

FDA shared details regarding factors that had contributed to the size of the FY 2020 carryover balance. These factors include: \$69M in excess earned revenue (i.e., earned revenue in excess of inflation-adjusted statutory revenue targets) that the Agency received in FY 2020; \$19M in unearned revenue that became earned during FY 2020; and \$4M in recoveries (i.e., money that was obligated to MDUFA but was then de-obligated). FDA also reiterated the information that it had provided in working group meetings that the size of the carryover balance increased in recent years as CDRH spent an increasing amount of non-user-fee appropriations ("budget authority") on the program. Beginning in 2017, FDA recognized the need to make smart, strategic investments to modernize the device program's information technology (IT) infrastructure. And, when budget authority must be spent all in one year, it is difficult to do this. FDA spent additional budget authority on other aspects of the MDUFA program and returned user fees to the carryover balance that the Agency planned to use to support these future investments.

COVID-19 Supplemental Funding

FDA explained that COVID-19 supplemental funding received by the Agency will be used to support a broad range of pandemic response efforts. FDA discussed the portion of those funds currently allocated for COVID-19 premarket review work (e.g., review of emergency use authorizations).

Industry Presentation

Industry offered initial comments on the Agency's presentation and noted that its own presentation would not incorporate the additional information FDA had provided.

Industry began by reviewing the principles underlying the MDUFA user fee program:

- 1) Supporting timely patient access to safe and effective medical devices, and to maintain the U.S. review process as the gold standard in the world for patient safety;
- 2) That Congressional appropriations remain the primary source of funding for the device review program;
- 3) That user fees are used solely for the premarket review process and are used for agreed purposes, while Industry is supportive of additional general appropriations for patient safety as well as other appropriate postmarket initiatives;
- 4) Recognition that Industry has made significant and material investments in building up the program through MDUFA I through IV, such that there has been a sizable growth in resources and the program is now on very stable footing; and,
- 5) That user fees should support mutually shared goals and process improvements to help achieve timely patient access to safe and effective devices. Industry emphasized its commitment to device safety and the numerous provisions in the MDUFA commitment letter addressing safety.

The presentation then addressed Industry's proposal for the use of carryover balances available for use. Industry indicated its appreciation for FDA agreeing that there would be mutual discussion about the use of that funding. Industry expressed its expectation that the entire amount available for use, approximately \$209 million, would be discussed, and noted the MDUFA IV commitment letter's provision stating that, "If the collections are in excess of the resources needed to meet performance goals given the workload, or in excess of inflation-adjusted statutory revenue targets, FDA and Industry will work together to assess how best to utilize those resources to improve performance on submission types with performance goals and/or quality management programs...." Industry also noted the 2019 financial report indicated that carryover funds would be used for various core review functions.

With regard to use of those carryover funds, Industry proposed that specific uses be discussed and agreed to relating to enhancements to support reviews and pre-submission volume and process; citation of scientific justification in Additional Information/Major deficiency letters; time-to-decision (TTD) goals, and potentially for further investment in the initiatives funded as one-time costs under MDUFA IV. Industry expressed appreciation for the information FDA previously provided on IT enhancements funded under MDUFA IV. For this and other one-time costs, Industry proposed a discussion with FDA that included a full accounting of the use of the allocated resources, whether applicable MDUFA IV commitments were met, defined success measures for any future investments, and a specific proposal for any such initiative to be funded in MDUFA V. Industry re-stated its interest in adding a one-time investment in an independent audit of MDUFA program financing.

Administrative

Industry requested further details and resource needs from FDA's previously described proposals and FDA expressed willingness to present resource estimates at future meetings. FDA and Industry agreed to establish work group meetings focused on Third Party Review Program, Standards Program, Patient Science and Engagement Program, retention and recruitment, and further discussion for how to use the carryover balance.

Next Meeting

The next meeting is scheduled on July 21, 2021.

Meeting End Time: 4:00 pm EST