

Summary of Public Comments and Explanation of Changes to the MDUFA V Recommendations

Executive Summary

The Medical Device User Fee Amendments (MDUFA) authorize the U.S. Food and Drug Administration (FDA or Agency) to collect user fees for the process for the review of device applications. The current authorization for MDUFA expires on October 1, 2022. To develop recommendations for the current reauthorization of MDUFA (MDUFA V), FDA has followed the process described by statute, including holding two public meetings with associated dockets for public comment, conducting negotiations with regulated industry, and having monthly consultation meetings with public stakeholders (including patient and consumer advocates) while negotiations were ongoing.

The process used to develop the recommendations for the reauthorization provided a significant opportunity for stakeholders and other members of the public to express their views and priorities. FDA considers this input important to the shaping of the proposed recommendations for program enhancements.

After negotiations with regulated industry, the statute requires FDA to present the recommendations to specified Congressional committees; publish such recommendations in the *Federal Register*; provide for a period of 30 days for the public to provide written comment on such recommendations; hold a meeting at which the public may present its views on such recommendations; and after consideration of such public views and comments, revise the recommendations as necessary.

On March 22, 2022, FDA posted on its website the draft recommendations for reauthorizing MDUFA and announced the opening of a 30-day period for public comment. On April 7, 2022, FDA published the associated *Federal Register* notice announcing the recommendations and the public meeting, which was held on April 19, 2022. FDA also provided the draft recommendations to the Committee on Energy and Commerce of the House of Representatives (the House E&C Committee) and the Committee on Health, Education, Labor, and Pensions of the Senate (the Senate HELP Committee). FDA has considered the views and comments received pursuant to these processes, and we have revised the agreement as necessary. When transmitting the recommendations to Congress, the statute requires inclusion of a summary of the public views and comments received and any changes made to the recommendations in response to these views and comments. This document fulfills that statutory requirement.

Overall, the majority of comments received during the public meeting and via the docket reflected general support for the draft recommendations for reauthorization. Numerous groups reflecting patient advocates, physicians, and scientific or academic perspectives expressed their support for the MDUFA reauthorization generally and many of the proposed MDUFA V commitments. The most cited areas of support were for the draft commitments related to enhancing programs for patient science and engagement, digital health, and the use of real world evidence to support regulatory decision-making.

In addition, some commenters expressed concern about the agreement. The most cited areas of concern were that the draft recommendations did not provide for user fees and performance goals to support strengthened postmarket device safety activities, including enhanced support for adverse event monitoring and device recalls; that the negotiations did not provide additional mechanisms for non-industry stakeholder input; and that device registration fees put a financial burden on small businesses. In addition, during a hearing of the Senate HELP Committee on April 26, 2022, concern was expressed that the draft commitments related to the Total Product Lifecycle Advisory Program Pilot (TAP Pilot) did not include quantitative performance metrics.

Some stakeholders also provided advice or other input for FDA to consider as it implements the commitments. Finally, some comments, such as those on broader device program operations and specific regulatory policies, are outside the scope of the MDUFA reauthorization discussions, which are focused on performance goals and procedures for the review of medical device premarket submissions. FDA considers these views, as appropriate, even if it may not be able to consider them as part of the user fee agreement's reauthorization recommendations.

This document provides a summary of the 10 written comments submitted to the public docket before the close of the comment period, which included comments from a variety of different groups: medical device companies, trade associations, patient groups, consumer advocacy groups, and academic and professional organizations. In addition, this document describes the changes made to the Commitment Letter in consideration of the comments received and due to technical corrections that FDA identified after the draft recommendations were published.

Summary of Public Comments

Staffing needs

Several commenters noted their support that the MDUFA V agreement includes additional resources to support hiring and retention of staff. FDA agrees that adequate staffing is essential to helping the Agency fulfill its public health mission, including through administration of the MDUFA program, and we appreciate stakeholders' support.

Patient science and engagement

Several commenters noted their support for the MDUFA V agreement's inclusion of activities to continue and enhance the patient science and engagement program. (Commitment Letter, Section V.E.) In addition, during the public meeting, stakeholders recommended that FDA enhance coordination and collaboration among FDA centers as appropriate to advance patient science and engagement efforts. FDA notes that this activity already occurs, and we agree that the MDUFA V Commitment Letter should explicitly capture this activity in response to stakeholder input. Accordingly, the Commitment Letter, section V.E., has been updated with the following underlined language: "Where appropriate, the Agency will leverage collaborations and partnerships with patients, healthcare providers, industry, and others, as well as collaborations across FDA Centers, to advance these actions." In addition, commenters recommended that FDA continue to engage patients and patient organizations, including a diverse range of patients, as the Commitment Letter is implemented. FDA appreciates this input and will consider it as the

Agency develops its implementation plans, to the extent consistent with the reauthorization legislation that is passed into law.

Real world evidence

Commenters also supported the MDUFA V agreement's commitment to advancing development of real world data (RWD) and real world evidence (RWE) for regulatory acceptance for premarket submissions. (Commitment Letter, Section V.F.) This included support for use of MDUFA V resources to continue FDA's involvement with the Coordinating Committee for the National Evaluation System for health Technologies (NEST) and the Medical Device Innovation Consortium (MDIC). In addition, commenters recommended additional transparency on avenues available to researchers, health data organizations, and other non-industry stakeholders to interact with FDA to advance innovative methodology approaches with respect to RWE development and analysis. FDA appreciates this input and will consider it as the Agency develops its implementation plans, to the extent consistent with the reauthorization legislation that is passed into law.

Digital health

Commenters supported the MDUFA V agreement's commitment to building its digital health expertise and advancing regulatory science related to digital health technologies. (Commitment Letter, Section V.G.) In addition, commenters at the public meeting recommended that the agreement include a commitment to engage stakeholders to explore regulatory approaches to digital health technologies. FDA agrees that the MDUFA V Commitment Letter should explicitly capture this activity in response to stakeholder input. Accordingly, the Commitment Letter, section V.G., has been updated to include the following new commitment: "Engage with stakeholders, including patients, users, and industry, through roundtables, informal meetings, and teleconferences to explore regulatory approaches to digital health technologies."

Total Product Life Cycle (TPLC) Advisory Program (TAP Pilot)

During a hearing of the Senate HELP Committee on April 26, 2022, concern was expressed that commitments related to the TAP Pilot (Commitment Letter, Section V.J.) did not include quantitative performance metrics. In consideration of those comments, the Commitment Letter has been revised to include three performance goals: (1) FDA will engage in a teleconference with the participant on requested topic(s) pertaining to the TAP device within 14 days of the request for 90% of requests for interaction; (2) FDA will provide written feedback on requested biocompatibility and sterility topics(s) pertaining to the TAP device within 21 days of the request for 90% of such requests for written feedback; and (3) FDA will provide written feedback on requested topic(s) pertaining to the TAP device other than biocompatibility and sterility within 40 days of the request for 90% of requests for written feedback. These goals address the objective of the TAP Pilot to provide more frequent, fluid interactions with sponsors than is contemplated and resourced for existing programs. These performance goals would begin in the second year of MDUFA V, when the TAP Pilot begins to enroll a sufficient number of products for these measures to be meaningfully tracked. Additional conforming edits were made in Section V.J of the Commitment Letter to reflect this revision.

Postmarket device safety

Commenters from patient and consumer advocacy organizations expressed concern that the MDUFA V agreement does not include funding and performance goals related to postmarket device safety. Commenters recommended that the agreement include postmarket safety-related commitments, including commitments to strengthen postmarket surveillance; to monitor postmarket clinical trials; to improve the speed of device recalls; to reflect performance metrics based on postmarket events; and to reflect enhanced reporting of postmarket activities to the public.

Section 737(9) of the FD&C Act defines the “process for the review of device applications,” which are the activities included within the scope of MDUFA on which user fees can be spent. With certain enumerated exceptions, such as evaluation of postmarket studies required for devices approved under a premarket approval application (PMA), this definition generally does not include postmarket safety activities. Many of the commenters’ postmarket safety-related recommendations fall outside of the current scope of this definition. Although FDA proposed postmarket safety-related commitments during MDUFA V negotiations, FDA and Industry ultimately did not agree to those proposals and an associated expansion of the statutory definition. For these reasons, the MDUFA V final recommendations do not include any commitments related to the Agency’s work on postmarket device safety.

Small business fees

FDA received two comments regarding the establishment registration fee, which is assessed annually on all device manufacturers that are required to register. The commenters requested a reconsideration of this fee for small businesses with modest annual revenues. Although businesses that meet the definition of a “small business” are eligible for certain reduced or waived premarket submission user fees, the statute does not provide for a reduced or waived establishment registration fee for any business, nor did the MDUFA V draft recommendations include any such reduction or waiver. The fee amounts and fee structure (the schedule of fees paid for certain submissions or activities), including the annual establishment registration fee, are designed to balance the need for stable and reliable funding for FDA with the need to reduce barriers to market entry and encourage innovation. Fees support FDA’s process for the review of device applications by providing resources to, among other things, hire staff with needed expertise, modernize information management systems, facilitate additional interactions between FDA and applicants, and provide more guidance to prospective applicants. Such activities ultimately allow FDA to review medical devices for safety and effectiveness more rapidly, predictably, consistently, and transparently. This benefits sponsors and manufacturers of all sizes, the health care community, and (most importantly) patients. For these reasons, the MDUFA V final recommendations do not include any changes to the establishment registration fee structure.

Concerns over other aspects of the MDUFA V agreement

Commenters also expressed other concerns regarding aspects of the MDUFA V agreement. Some commenters criticized the long-standing practice of review goals, which commenters characterized as an emphasis on fees and speed. FDA notes that these review goals have been a part of the prior MDUFA agreements and are not unique to this MDUFA.

Some commenters also requested more transparency for non-industry stakeholders as part of the negotiations. FDA notes that the statute prescribes a process for stakeholder consultation, and, consistent with that process, FDA conducted two public meetings, held 12 stakeholder consultation meetings, and considered stakeholder feedback in the development of proposals and in revising the Commitment Letter as described in this summary.

The majority of commenters acknowledged the importance of the MDUFA program to ensure that FDA has necessary resources, and they were appreciative of the opportunity for the Agency to seriously consider their feedback and input.

Other comments

Other comments were outside the scope of the current MDUFA reauthorization. These comments related to activities that cannot be supported by MDUFA user fees under statute, encompass broader operations beyond the MDUFA program, or involve changes to specific regulatory policies. Examples of such comments include a recommendation to require submission of data from randomized, well-controlled clinical trials in a PMA for all high-risk, permanently implantable devices and a recommendation to request budgetary resources to strengthen postmarket activities and manufacturing inspections.

Other technical changes to the Commitment Letter

FDA made two technical changes to the commitment letter to correct inadvertent errors in the draft agreement that was posted for public comment.

In Section II.A for Pre-submissions, FDA added clarification of on-going activities to train managers and staff on the updated guidance. FDA regularly trains staff and managers on new and updated guidances.

In Section VIII.G, FDA corrected an error of the percentage in the last sentence to match the percentage at which the MDUFA V cohort for PMAs would be closed. Per the definition of the MDUFA cohort for PMAs, a cohort for a FY is closed when 95% of the MDUFA V cohort has reached a MDUFA decision, which is the same as in MDUFA IV.