4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-6655]

Medical Device User Fee Amendments; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a hybrid public meeting titled "Medical Device User Fee Amendments." The purpose of the public meeting is to discuss proposed recommendations for the reauthorization of the Medical Device User Fee Amendments (MDUFA) for fiscal years (FYs) 2028 through 2032. MDUFA authorizes FDA to collect fees and use them for the process for the review of device applications. The current legislative authority for MDUFA expires September 30, 2027. At that time, new legislation will be required for FDA to continue collecting device user fees in future fiscal years. Following discussions with the device industry and periodic consultations with public stakeholders, the Federal Food, Drug, and Cosmetic Act (FD&C Act) directs FDA to publish the recommendations for the reauthorized program in the *Federal Register*, hold a meeting at which the public may present its views on such recommendations, and provide for a period of 30 days for the public to provide written comments on such recommendations. FDA will then consider such public views and comments and revise such recommendations as necessary.

DATES: The public meeting will be held in person and virtually on August 5, 2026, from 10 a.m. to 3 p.m. Eastern Time. The draft commitment letter is posted in the docket and also on this website at: https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa-fees/medical-device-user-fee-amendments-2028-mdufa-vi. The docket will close 30 days after those documents are made publicly available. Submit electronic or written comments to the

public docket within 30 days of publication. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public meeting will be held in person at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the White Oak Great Room, Silver Spring, MD 20993-0002 and virtually using the Microsoft Teams platform. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. Participants must be REAL ID compliant to access federal facilities. For additional information regarding REAL ID, refer to https://www.dhs.gov/real-id/real-id-faqs. For security and parking information, please refer to https://www.fda.gov/about-fda/visitor-information/public-meeting-information and https://www.fda.gov/about-fda/visitor-information/visitor-parking-and-campus-map.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time, 30 days after the date of publication of this notice in the *Federal Register*. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in

the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2026-N-6655 for "Medical Device User Fee Amendments; Public Meeting; Request for Comments." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out,

will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Nia Ramsey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5422, Silver Spring, MD 20993-0002, 301-796-5424, MDUFAVIReauthorization@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a hybrid public meeting to discuss proposed recommendations for the reauthorization of MDUFA, which authorizes FDA to collect user fees to support the process for the review of device applications, which reaches various components in FDA, including the Center for Devices and Radiological Health (CDRH), the Center for Biologics Evaluation and Research (CBER), the Office of the Commissioner (OC), and the Office of Inspections and Investigations (OII). The current authorization of the program (MDUFA V) expires September 30, 2027. At that time, new legislation will be required for FDA to continue collecting device

user fees for future fiscal years to provide funds for the process for the review of device applications. As required by section 738A(b)(1), (2), (3), and (7) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379j-1(b)(2), (3), and (7)), FDA obtained prior public input and negotiated an agreement with regulated industry while periodically consulting with scientific and academic experts, health care professionals, and representatives of patient and consumer advocacy groups, and making minutes of negotiation and stakeholder consultation meetings publicly available. Section 738A(b)(5) of the FD&C Act (21 U.S.C. 379j-1(b)(5)) requires that, after holding negotiations with regulated industry, FDA take the following actions: (1) present the recommendations to the Committee on Energy and Commerce of the U.S. House of Representatives and the Committee on Health, Education, Labor, and Pensions of the U.S. Senate; (2) publish the recommendations in the *Federal Register*; (3) provide a period of 30 days for the public to submit written comments on the recommendations; (4) hold a meeting at which the public may present its views on the recommendations; and (5) after consideration of public views and comments, revise the recommendations as necessary. This notice, the 30-day comment period, and the public meeting will satisfy parts of these requirements. After the public meeting and 30-day comment period, FDA will revise the recommendations as necessary. In addition, the Agency will present the recommendations to the Congressional committees.

The purpose of the meeting is for the public to present its views on the proposed recommendations for the reauthorized program (MDUFA VI). In general, the meeting format will include a brief presentation by FDA, but will focus on hearing from different stakeholder interest groups (such as patient advocates, consumer advocates, industry, health care professionals, and scientific and academic experts). The Agency will also provide an opportunity for individuals to make presentations at the meeting and for organizations and individuals to submit written comments to the docket before and after the meeting. The following information is provided to help potential meeting participants better understand the

history and evolution of the medical device user fee program and the current status of the proposed MDUFA VI recommendations.

II. MDUFA V Performance Summary

The MDUFA V agreement enabled FDA to continue making progress on reducing review times and bringing devices to patients more quickly, while also enabling FDA to move forward in critical areas. FDA's performance was strong during the first year of MDUFA V (FY 2023), meeting almost all MDUFA V commitment letter goals and working to reduce the time for patients to have access to safe, new, innovative devices. During this time, FDA achieved all 14 of our submission review goals for which sufficient submissions were received to calculate performance, met 15 of 16 performance enhancement goals, and FDA and industry met one of two shared outcome goals.

FDA's performance continues to be strong during the second and third year of MDUFA V (FY 2024 and FY 2025). Preliminary performance data through September 30, 2025, including completed and pending reviews, indicate that FDA has met, or has the potential to meet, all 15 of the FDA's submission review goals for FY 2024 and all 13 of the FDA's submission review goals for FY 2025 for which FDA received sufficient submissions to calculate performance. FDA and industry missed one shared outcome goal for FY 2024; the remaining FY 2024 goal and both FY 2025 shared outcome goals are not yet sufficiently complete to determine the outcome. In addition, FDA had 16 performance enhancement goals due in FY 2024, of which 15 were completed on time and one was completed late. In FY 2025, FDA had 18 performance enhancement goals, of which 14 were completed on time, and four were missed.

Information about FDA's performance is available in the yearly and quarterly MDUFA performance reports, which are online at: http://www.fda.gov/about-fda/user-fee-performance-reports/mdufa-performance-reports and http://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/mdufa-reports.

User fees and related performance goals have played an important role in providing resources and supporting the management systems to ensure that safe and effective medical devices are available to patients in a timely manner.

III. Proposed MDUFA VI Recommendations

In preparing the proposed recommendations to Congress for MDUFA reauthorization, FDA conducted discussions with the device industry and consulted with stakeholders, as required by the FD&C Act. The Agency began the MDUFA reauthorization process by publishing a notice in the *Federal Register* requesting public input on the reauthorization and announcing a public meeting that was held on August 4, 2025. The meeting included presentations by FDA, and a series of panels with representatives of different stakeholder groups, including patient and consumer advocacy groups, regulated industry, and health care professionals. The materials from the meeting, including presentation slides and a transcript, can be found at: https://www.fda.gov/medical-devices/medical-devices-news-and-events/register-fdas-public-meeting-reauthorization-medical-device-user-fee-amendments-08042025.

From October 2025 through March 2026, FDA conducted negotiations with representatives of the device industry: the Advanced Medical Technology Association and the Medical Device Manufacturers Association. During negotiations with regulated industry, FDA also held monthly consultations with representatives of patient and consumer advocacy groups, health care professionals, and scientific and academic experts. Minutes of these meetings are posted on FDA's website at: https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa-fees/medical-device-user-fee-amendments-2028-mdufa-vi.

The proposed recommendations for MDUFA VI address many priorities identified by stakeholders and generally build on successful enhancements or refine elements from the existing program. Significant recommendations are briefly described below with reference to the applicable section of the draft commitment letter. FDA notes that until the final commitment letter is published the recommendations remain subject to change.

A. Shared Outcome Goals

FDA proposes to continue reporting, on an annual basis, the average Total Time to Decision for premarket approval applications (PMAs) and 510(k) submissions, with a shared outcome goal of 285 calendar days for original PMA and panel-track supplement submissions throughout FYs 2028 through 2032, and a 510(k) shared outcome goal that ramps down from 128 calendar days in FY 2028 to 112 calendar days by FY 2032. Additional details regarding the shared outcome goals can be found in Section I of the draft commitment letter.

B. Review Performance Goals

The draft MDUFA VI commitment letter largely maintains the review performance goals established by the end of MDUFA V, reflecting FDA's commitment to sustaining the high level of review performance achieved over the course of the prior agreement. The core decision and interaction goals for the majority of submission types--including Original PMAs, 180-Day and Real-Time PMA Supplements, 510(k)s, CLIA Waiver by Application submissions, and all biologics license application-related submission types--remain unchanged from MDUFA V.

C. Pre-Submissions

FDA proposes to continue the Pre-Submission program under MDUFA VI to address increasing submission volume, maintaining a performance goal of providing written feedback on at least 90 percent of Pre-Submissions within 70 days or 5 calendar days prior to the scheduled meeting, whichever comes sooner, for up to 5,000 submissions per fiscal year. A significant new feature of MDUFA VI is the introduction of Focused Follow-Up Pre-Submissions--a new, faster-turnaround submission type intended to address targeted follow-up questions related to a prior Pre-Submission, with a written response provided within 45 calendar days of receipt. In conjunction with the proposed enhancements and performance goals outlined in the draft commitment letter, FDA and industry agreed to proposed changes to the FD&C Act to include a fee for initial Pre-Submissions, to promote efficient use of the program, and for which sponsors will later receive a corresponding credit on certain related subsequent marketing submission fees.

Additional details regarding Pre-Submissions can be found in Section II.A of the draft commitment letter.

D. De Novo Requests

FDA proposes to maintain a De Novo decision goal of 90 percent of De Novo requests receiving a MDUFA decision within 150 FDA days. MDUFA VI introduces a structured Introduction Meeting between FDA and the applicant within the first 30 FDA days of review, intended to promote early alignment and review efficiency, and recognizes the possibility of issuance of a "Not Grantable" letter, with a final determination to decline or grant the submission within 75 calendar days but no longer than 90 calendar days after receipt of the response to the not grantable letter. Additional details regarding De Novo requests can be found in Section II.E of the draft commitment letter.

E. Infrastructure

FDA proposes several infrastructure enhancements under MDUFA VI to support the process for the review of device applications. FDA will continue to recruit, hire, and retain sufficient technical and scientific staff and will leverage contractual support. MDUFA VI also facilitates significant enhancements to IT infrastructure, including improvements to the Customer Collaboration Portal, development of an interactive Navigator tool to guide stakeholders to appropriate communication channels, and a new online mechanism for direct engagement between FDA and applicants. A key element of MDUFA VI is the establishment of a Resource Capacity Planning and Management capability to support data-driven resource management decisions, with an Implementation Plan to be published by March 31, 2029. FDA also proposes changes to optimize MDUFA's statutory appropriation and spending trigger provisions. Additional details regarding infrastructure can be found in Section III of the draft commitment letter.

F. Deficiency Letters

To support improved communication in letters requesting additional information, FDA will continue to train staff and managers on applicable guidance and best practices for clear and least burdensome deficiency communication, and will maintain a performance goal of providing a statement of the basis for the deficiency in 95 percent of deficiency letters each fiscal year for Original PMA, Panel-Track Supplement, 510(k) and De Novo request submissions. A new feature of MDUFA VI is the development of a survey for recipients of deficiency letters to gather feedback on deficiency communication quality, with results used to inform improvement activities. Additional details can be found in Section IV.B of the draft commitment letter.

G. Review Consistency

A new commitment under MDUFA VI, FDA proposes to advance efforts to improve review consistency to facilitate efficient, effective, and appropriately consistent submission review practices across and within Offices of Health Technology (OHTs). FDA proposes to make improvements in at least one specific, high-impact topic area each fiscal year, with a minimum of eight topics addressed across the five-year period. Each fiscal year, industry will provide FDA with a prioritized list of topic areas for consideration, and FDA will report annually to industry on the actions taken and their effectiveness. Additional details regarding review consistency can be found in Section IV.C of the draft commitment letter.

H. Enhanced Use of Consensus Standards

FDA proposes to further mature the Accreditation Scheme for Conformity Assessment (ASCA) program by expanding the range of standards and device categories covered, enhancing training for staff and accredited testing laboratories, and working with stakeholders on programmatic improvements. FDA also proposes to advance the development and recognition of regulatory-ready consensus standards, including through enhanced reviewer training, improvements to review tools and templates, and continued development of regulatory science tools. The draft MDUFA VI commitment letter emphasizes public-private collaboration in the development and optimization of consensus standards, committing FDA to attend industry

meetings at least twice annually to discuss standards of mutual interest, work with industry and testing laboratory representatives to improve the reproducibility and repeatability of analytical methods, and engage with stakeholders to identify opportunities to ensure standards are regulatory-ready and optimized for regulatory use. Additional details regarding the enhanced use of consensus standards can be found in Section IV.D of the draft commitment letter.

I. Third Party Review Program

FDA proposes to continue to support the Third Party Review program with the objective of eliminating routine re-review by FDA. FDA will continue to provide training for Third Parties seeking accreditation, audit and provide tailored re-training to accredited Third Parties, and publish performance of individual accredited Third Parties on FDA's website. Additional details regarding the Third Party Review program can be found in Section IV.E of the draft commitment letter.

J. Patient Science and Engagement

FDA proposes to continue to advance the Patient Science and Engagement program by expanding scientific expertise and staff capacity to respond to growing submission volume and complexity of patient science data, expanding training internally and externally on clinical outcome assessments and patient engagement in device clinical studies, supporting the use of innovative technologies to capture patient perspectives and reduce patient burden, and developing case examples of the use and impact of patient-generated health data (PGHD) in device development. Additional details regarding patient science and engagement can be found in Section IV.F of the draft commitment letter.

K. Real World Evidence (RWE)

FDA proposes to continue to advance the development of Real-World Data (RWD) and RWE methods and approaches to support regulatory acceptance for premarket submissions, with user fee revenue devoted solely to premarket RWE activities. FDA will continue to advance CDRH's RWD/RWE training program, update stakeholders on RWE program activities at two

or more open public meetings during the course of MDUFA VI, and annually publish examples of market authorization decisions that relied on RWD/RWE. FDA will continue to invest in National Evaluation System for Health Technology activity and hire internal RWE experts across OHTs to support consistent and coordinated review of RWD/RWE-related submissions. Additional details regarding RWE can be found in Section IV.G of the draft commitment letter.

L. Digital Health

FDA proposes to continue building its digital health expertise and working to streamline and align FDA review processes with software lifecycles for digital health products, principally through the Digital Health Center of Excellence. Key proposed actions include expanding technical expertise to address rapidly evolving digital health technologies; strengthening reviewer training for consistent, high-quality reviews; and engaging with stakeholders through formal and informal mechanisms to explore regulatory approaches to emerging digital health technologies. Additional details regarding digital health can be found in Section IV.H of the draft commitment letter.

M. International Harmonization

A significant new feature of MDUFA VI is a proposed pilot in which the same device with the same intended use is submitted simultaneously to FDA and at least two other medical device regulatory authorities to support coordinated premarket review, with results to be evaluated and published by September 30, 2030. FDA proposes to advance efforts to promote appropriate reliance on scientific assessments performed by trusted regulatory authorities and to publish an Implementation Plan for international harmonization activities by the end of FY 2028. FDA also proposes to enhance international harmonization activities by expanding attendance, support, and leadership of international organizations of global importance, including the International Medical Device Regulators Forum . Additional details regarding international harmonization can be found in Section IV.I of the draft commitment letter.

N. Total Product Life Cycle (TPLC) Advisory Program (TAP)

Building on lessons learned from the TAP Pilot established under MDUFA V, FDA proposes to transition to a sustainable, full TAP program covering all product areas, with voluntary enrollment targeted to eligible devices across all OHTs no later than October 1, 2027. TAP will continue to focus on enhancing the Breakthrough Device review experience by providing more timely and robust premarket interactions, facilitating improved strategic decision-making during device development, and collaborating to align expectations regarding evidence generation and submission quality. A new feature of MDUFA VI is focused engagement and collaboration between FDA and the Centers for Medicare and Medicaid Services for technologies for which a new coverage determination would be beneficial. Additional details regarding TAP can be found in Section IV.J of the draft commitment letter.

O. Performance Reports

FDA proposes to continue to report quarterly and annually on performance against commitments, including submission review metrics at the OHT and Center level, staffing and hiring data, guidance document status, fee collections, and progress on key program areas including TAP, RWE, international harmonization, ASCA, and review consistency. Additional details regarding performance reporting can be found in Section V of the draft commitment letter.

Additional commitments not summarized above are described in the full MDUFA VI commitment letter, available at: https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa-fees/medical-device-user-fee-amendments-2028-mdufa-vi .

FDA will post the agenda approximately 5 days before the meeting at: https://www.fda.gov/medical-devices/medical-devices-news-and-events/register-fdas-public-meeting-reauthorization-medical-device-user-fee-amendments-08052026.

Registration: Registration is free and based on space availability, with priority given to early registrants. People interested in attending the Medical Device User Fee Amendments public meeting must register online by 4 p.m. July 20, 2026. Early registration is recommended

because seating is limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration will be provided on the day of the meeting beginning at 8 a.m. If you need special accommodation because of a disability, please contact Nia Ramsey (see FOR FURTHER INFORMATION CONTACT) no later than July 17, 2026. To register for the meeting, please visit: https://www.fda.gov/medical-devices/medical-devices-news-and-events/register-fdas-public-meeting-reauthorization-medical-device-user-fee-amendments-08052026 Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. Registrants will receive confirmation after they have been accepted.

Opportunity for Public Comment: Those who register will have an opportunity to participate in the public comment session of the meeting. If you wish to speak during the public comment session, follow the instructions in the notification and identify which topic(s) you wish to address. All requests to make public comments during the meeting must be received by July 20, 2026, at 11:59 p.m. Eastern Time. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate comment and request time jointly. We will determine the amount of time allotted to each commenter, and the approximate time each comment is to begin, and will select and notify participants by July 27, 2026. If selected for presentation, any presentation materials must be emailed to Nia Ramsey (see FOR FURTHER INFORMATION CONTACT) no later than July 30, 2026, at 4:00 p.m. No commercial or promotional material will be permitted to be presented at the public meeting.

FDA is holding this meeting to provide information on the proposed recommendations for the reauthorization of MDUFA for FYs 2028 through 2032. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the meeting topics. The docket will remain open 30 days after the publication of this notice. The draft commitment letter is posted in the docket and also on this

website at: https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa-fees/medical-device-user-fee-amendments-2028-mdufa-vi.

Streaming Webcast of the Public Meeting: This meeting will also be webcast. The meeting link is: https://teams.microsoft.com/l/meetup-join/19%3ameeting_ZDY3YWY1MDctNDU2MS00YjQyLTg2MTAtMmU3OGVjMzgzMDJl%40thread.v2/0?context=%7b%22Tid%22%3a%227d2fdb41-339c-4257-87f2-a665730b31fc%22%2c%22Oid%22%3a%22f46007e5-06e8-46b8-8ed0-45459ca51924%22%7d. Organizations are requested to register all participants, but to view using one connection per location.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible in the docket at http://www.regulations.gov. It may be viewed at the Division of Dockets Management (see ADDRESSES). A link to the transcripts will also be available on the Internet at: https://www.fda.gov/medical-devices/medical-devices-news-and-events/register-fdas-public-meeting-reauthorization-medical-device-user-fee-amendments-08052026.

Notice of this meeting is given pursuant to 21 CFR 10.65.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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