Medical Device User Fee Amendments FY2028-2032 (MDUFA VI)

Background: Under MDUFA, medical device manufacturers pay fees to the FDA when they register their establishments with the agency or submit to market a new medical device in the U.S. and for certain other types of submissions.

MDUFA VI represents a commitment to increase the efficiency of regulatory processes in order to bring safe and effective medical devices to the U.S. market. The draft recommendations are the result of more than a year of public input, negotiations with representatives of regulated industry and parallel consultations with stakeholders, including patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts.

At A Glance:

Fee Amounts: Maintains stable fee levels through FY2032 to improve predictability and support the FDA's critical public health work.

- The vast majority of the MDUFA VI financial footprint will carry forward the core MDUFA V user fee program, reallocating fee revenue to MDUFA VI priorities while decreasing domestic registration and marketing submission fees.

Fee Structure: Reforms to enhance American competitiveness and support small businesses.

- The FDA is implementing fee structure changes to ensure foreign firms are contributing an appropriate share of user fee revenue given the additional resources required to oversee foreign firms marketing devices in the U.S.
- Qualifying U.S. small businesses with U.S. tax returns may qualify for fee reductions and waivers for marketing submissions as well as a new registration fee waiver that would no longer require firms to demonstrate financial hardship.
- With these changes, fee amounts for all submission types (e.g., PMA, De Novo, 510(k)) are slated to decrease in FY2028; U.S.-based firms, among others, will see total fees coming down.

Premarket Performance: MDUFA VI maintains high performance across all review goals.

- **Performance Goals:** The FDA has committed to continuing the high-performance goals set during MDUFA V – at or above 90% in all cases.
- **Pre-Submission Program:** To encourage more strategic utilization of the program, MDUFA VI features a modest $2,000 fee for certain initial Pre-Subs, which will be credited back in the subsequent marketing submission fee. Other key enhancements include a focused written feedback option with a 45-day timeline (for applicants with narrow, follow-up questions related to a recent Pre-Sub), and an option to request supervisory review if submitters believe they have received inconsistent feedback.

- **De Novo Classification:** Targeted enhancements aimed at improving the efficiency of the review process include a "walkthrough" meeting within the first 30 days, a new "not grantable" decision option, and extended time for applicants to address submission deficiencies, among other changes.
- **Review Consistency:** Building on the success of continuous improvement in MDUFA V, the FDA has committed to further strengthening the existing deficiency writing efforts and expanding this work to target review consistency across 8 topic areas during MDUFA VI.

Programmatic Enhancement: MDUFA VI proposes simplifications to improve efficiency and customer experience across key programs. The draft recommendations have no new major initiatives but instead focus on strengthening proven activities under MDUFA.

- **Real World Evidence (RWE):** MDUFA VI advances RWE availability and use for premarket purposes, including continued support for the National Evaluation System for health Technologies (NEST).
- **Consensus Standards:** MDUFA VI advances the use of consensus standards to promote more efficient, predictable, and globally aligned reviews. The draft agreement would reinvest in the FDA's Accreditation Scheme for Conformity Assessment (ASCA) and public-private collaboration in early standard development and recognition
- **Patient Science:** MDUFA VI further integrates patient perspectives into regulatory decision-making across clinical domains, expanding expertise and deepening impact of clinical outcome assessments (COAs), patient-generated health data (PGHD), and a range of other outcomes assessments.
- **International Harmonization:** MDUFA VI strengthens the FDA's global leadership in harmonization, helping to align regulatory approaches and reduce duplication. The draft agreement empowers the FDA to strengthen international endeavors within the International Medical Device Regulators Forum (IMDRF) in addition to bilateral reliance efforts and multi-lateral pilot projects to explore common submission templates.
- **Total Product Life Cycle (TPLC) Advisory Program (TAP):** In MDUFA VI, TAP transitions from a pilot to a permanent program with a streamlined footprint and refined scope of eligible innovators. TAP will function as a strategic bridge between the FDA and the Centers for Medicare & Medicaid Services (CMS), affording new opportunities for novel medtech developers to engage early with the agencies concurrently, particularly at the study design phase.
- **Digital Health:** MDUFA VI expands investment in CDRH's Digital Health Center of Excellence (DHCoE) specifically to ensure we keep pace with rapidly evolving technologies and maintain leadership across a rapidly expanding portfolio of AI- and software-enabled device technology. These additions are intended to promote accountability, predictability, and transparency for the medtech sector through structured pre-submission processes, earlier interactions, and increased communication during the review process and across the TPLC.

Strengthening Infrastructure and Harmonizing Programs: To make user fee programs simpler to administer and more transparent to the public, the FDA is taking steps to streamline processes (e.g. carryover balance), simplify statutory calculations (e.g. inflation methodologies), and provide greater transparency to those impacted by these programs.

- **IT Modernization:** MDUFA VI will launch an interactive *Navigator* tool for external stakeholders to find public information, navigate the agency, and track communications. The *Customer Collaboration Portal* (through which firms submit information to the FDA) will be improved with automated submission intake, real-time verification, and two-way communication.
- **Hiring and Staffing:** MDUFA V annual hiring targets and penalties will be replaced with greater transparency about how the agency is doing recruiting, onboarding, and retaining personnel. The MDUFA 5-year financial plan will be enhanced with streamlined data.
- **Resource Capacity Planning:** MDUFA VI features new resource capacity planning (RCP) functionality, with enhanced analytics, forecasting, and reporting capabilities to support data-driven staffing and resource allocation decisions to ensure review capacity is calibrated to meet MDUFA performance commitments and public health priorities as workload evolves.

MDUFA – By the Numbers:

- Over 21,000 total annual submissions in FY2025
  - 4151 510(k); 69 De Novo; 581 PMA originals, panel track supplements, 180-day supplements, and real-time supplements
  - Majority of 510(k) (51%) and De Novo (81%) submitters qualified as small businesses
- Approximately 30,000 registered device establishments in FY2025
  - 46% domestic; 54 % foreign
- Met or on track to meet 46 out of 48 performance goals for FY2023-2025*
  - A complete list of goals and performance is available in the FY2025 MDUFA Performance Report to Congress

**As of September 30, 2025*