

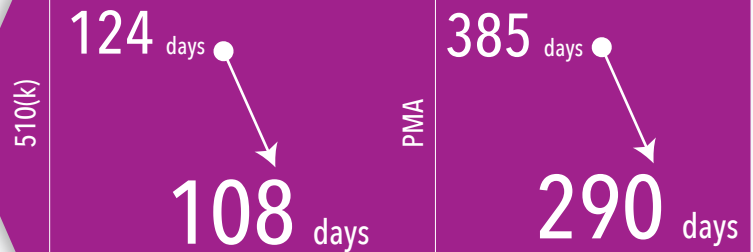
MEDICAL DEVICE USER FEE ACT REAUTHORIZATION

GOOD FOR PATIENTS | GOOD FOR FDA | GOOD FOR INNOVATION

The Medical Device User Fee Act (MDUFA) gives FDA the authority to collect user fees from industry to support review activities. Under the latest reauthorization agreement, industry will invest additional resources in FDA in return for meaningful performance goals to improve the efficiency, predictability and transparency of the agency's review process. These process improvements translate into more timely patient access to life-changing medical technologies.

IMPROVED TOTAL REVIEW TIMES

FDA committed to significant improvements for PMA and 510(k) total review time goals, including first-time goals for de novo products.



GREATER PATIENT INVOLVEMENT

Increased use of patient preference information (PPI) and patient reported outcomes (PROs) in premarket submissions will be encouraged.

USE OF REAL-WORLD EVIDENCE

A pilot project will assess the use of real-world evidence (RWE) to support premarket activities, including expanded indications for use, new clearances and approvals.



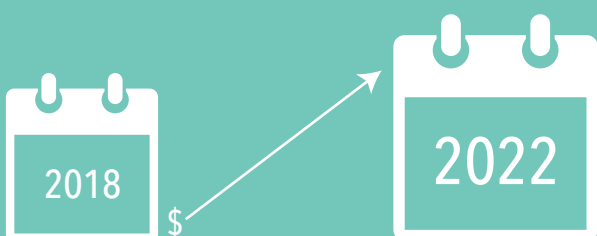
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PRE-SUBMISSION MEETING PROCESS IMPROVEMENTS

FDA will provide meaningful written feedback to companies at least five days prior to a scheduled product application pre-submission meeting.

CLARIFICATION FOR DEFICIENCY LETTERS

FDA will document the rationale for issuing a deficiency letter to a product sponsor – citing either a specific rule, guidance or standard, or a specific scientific issue.



NEW FUNDS FOR FDA

\$999.5 million to FDA over five years, including:
\$228 million in new resources
\$92.5 million for IT, infrastructure, training and other improvements

The user fee agreement is a **win-win-win** for patients, FDA, and innovation.