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PDUFA and MDUFA History

	PDUFA	MDUFA
Background	**In the '90s, FDA experienced backlogs in its drug approval process, delaying the launch of many drugs to market** **This led to "drug lag," whereby drugs were being approved abroad before becoming available for US patients**	**Before MDUFA, FDA's medical device program suffered a long-term, significant loss of resources that undermined the program's capacity and performance**
Purpose	**Increase the efficiency and timeliness of the drug approval process** **Supplement FDA budget with revenue from user fees** **Hold FDA responsible to meeting performance goals in the drug approval timelines**	**Ensure that safe and effective medical treatments will reach patients more rapidly** **Resourcing to ensure that devices marketed in the US continue to meet high standards for safety and effectiveness**
Key features	**PDUFA I: Reducing Application Review Time (FY 1993-1997)** • Allowed FDA to charge user fees in the form of Application, Establishment, and Product fees • FDA used additional user fee revenue to hire more reviewers and support staff **PDUFA II: Facilitating the Drug Dev. Process (FY 1998-2002)** • Reauthorized FDA user fees for another 5 years **PDUFA III: Refining the Process (FY 2003-2007)** • Gave FDA authority to use PDUFA resources on risk management and post market surveillance for up to 3 years after launch **PDUFA IV (FY 2008-2012)** • Increased user fees • Expanded FDA's authority to use funds for post market surveillance and risk evaluation and mitigation	**MDUFA I (FY 2003-2007)** • User fees for PMAs and 510(k)s pre-market reviews • FDA performance goals become more demanding over time • Establishment inspections may be conducted by accredited persons (third-parties), under carefully prescribed conditions. • New regulatory requirements for reprocessed single-use devices **MDUFA II (FY 2008-2012)** • Reauthorized user fees with more predictability • Established more rigorous performance goals for FDA • Decreased fees for small businesses

Source: FDA

The Prescription Drug User Fee Act (PDUFA) created a mechanism to add resources to the FDA

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Fees collected from industry

Type of fees

- Application
  - One-time fee for New Drug Applications (NDA) and Biologics License Application (BLA)
- Establishment
  - Annual fee for manufacturers
- Product
  - Annual fee for products on market

Adjustments to fees

- FDA determines annual fee increases
- Adjusted annually to take into account workload and inflation
- Application, establishment, and product fees each contribute one-third of the total fee revenues in a fiscal year

Use of fees

Hiring more Full-Time Employees (FTEs)

- Began under PDUFA I (1993-1997)
- FDA authorized to hire full-time drug reviewers
- FDA held to performance goals in accelerating the review process

Risk management review of drugs

- Began under PDUFA III (2003-2007)
- FDA authorized to make improvements to the scientific review of drugs
- Purpose is to evaluate efficacy and risk of drug

Post market surveillance

- Under PDUFA III
  - FDA responsible for tracking drug efficacy up to 3 years after launch
- Under PDUFA IV (2008-2012)
  - Elimination of 3-year time constraint, FDA responsible for all post-market surveillance

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The Medical Devices User Fee & Modernization Act (MDUFMA) created new funding & performance goals for devices

	MDUFMA I (FY 2003 – FY 2007)	MDUFMA II (FY 2008 – FY 2012)
Types of fees	• Various one-time application fees	• Introduced new fees while lowering application fee costs • New annual establishment fee for manufacturers • New annual product fee for devices on market
Adjustments to fees	• Fee increases varied from year to year depending on previous year's revenue	• 8.5% annual increase from 2008-2011
Small business discounts	• Decreased application fees for manufacturers that qualify as small businesses	• Extended to foreign small businesses
Use of fees	• Solely for the purpose pre-market approvals / clearances • Hiring more reviewers was the main cost driver	• Solely for pre-market evaluation • Separate appropriation for post-market surveillance
Performance goals	• Held FDA to performance goals in application review time. (“FDA clock”)	• More rigorous Agency performance goals, under “FDA clock.”