Medical Device User Fee Amendments of 2017 (MDUFA IV): An Introduction

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Overview

- Background of User Fee Legislation
- User Fees
- Performance Goals
- Program Highlights

Background of User Fee Legislation

Premise of User Fees

- **Industry agrees:**
  - to pay user fees for specific medical device submissions and other efforts
- **CDRH agrees:**
  - to increase Center resources
  - to make reviews more timely, predictable, and transparent to sponsors
- **Shared Commitment between CDRH and Industry**

Prior History of CDRH User Fees

Law	Years	Key Provisions
MDUFMA (MDUFA I)	**FY03 - FY07**	provided resources to support premarket review
MDUFA II	**FY08 - FY12**	added more aggressive performance goals
MDUFA III	**FY13 - FY17**	increased resources with different performance goal structure

MDUFMA = Medical Device User Fee and Modernization Act of 2002
MDUFA = Medical Device User Fee Amendments

MDUFA IV Timeline

July 13, 2015
Public meeting to solicit public input related to reauthorizing MDUFA

September 2015 – August 2016
FDA and industry negotiated commitments and funding amounts; FDA met with patient and consumer advocacy groups

November 6, 2016
Public meeting and revisions to agreement based on input from public meeting

January 5, 2017
HHS transmitted recommendations for reauthorization of MDUFA to Congress

August 18, 2017
President signed FDA Reauthorization Act of 2017 (FDARA), which includes the reauthorization of MDUFA

MDUFA IV References

- **Medical Device User Fee Amendments of 2017**
  - from FDA Reauthorization Act of 2017, Title II

www.congress.gov/bill/115th-congress/house-bill/2430/text?source=govdelivery&utm_medium=email&utm_source=govdelivery#toc-H22267DC488624A529119D9B0CA52549E

- **Federal Register Notice – Medical Device User Fee Rates for FY18**

www.federalregister.gov/documents/2017/08/29/2017-18378/medical-device-user-fee-rates-for-fiscal-year-2018

User Fees

MDUFA IV User Fees

- **Apply to:**
  - 510(k)s
    - except for Third Party Review
  - PMAs
    - related Class III submission types - PDP, PMR, BLA
    - original, supplements, annual reports
  - De Novo
  - 513(g)
  - Establishment Registration Fee

- **Reduced Fee for Qualified Small Businesses**
  - except for Establishment Registration Fee

MDUFA IV User Fees

- **From Fiscal Year 2018 – 2022**
  - October 1, 2017 – September 30, 2022

- **Announcement of Fees:**
  - Estimated for 5 years; adjusted for inflation to meet revenue target
  - Federal Register, approximately 60 days before start of next fiscal year

www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm452519.htm

- **Adds 217 FTEs by End of MDUFA IV**

Performance Goals

Shared Outcome Goals

510(k) Average Total Time to Decision

	MDUFA III					MDUFA IV				
	FY13	FY14	FY15	FYF16	FY17	FY18	FY19	FY20	FY21	FY22
Goal	135	135	130	130	124	124	120	116	112	108

PMA 3-Year Average Total Time to Decision

	MDUFA III					MDUFA IV				
	FY11-FY13	FY12-FY14	FY13-FY15	FY14-FYF16	FY15-FY17	FY16-FY18	FY17-FY19	FY18-FY20	FY19-FY21	FY20-FY22
Goal	395	395	390	390	385	320	315	310	300	290

Summary of Performance Goals

Submission Type	Action	FDA Review Days	Percent of Submissions to Meet FDA Days				
			FY18	FY19	FY20	FY21	FY22
510(k)s	Substantive Interaction	60	95%	95%	95%	95%	95%
	Decision	90	95%	95%	95%	95%	95%
De Novos	Decision	150	50%	55%	60%	65%	70%
Original PMAs and Panel Track Supplements	Substantive Interaction	90	95%	95%	95%	95%	95%
	Decision If No Panel	180	90%	90%	90%	90%	90%
	Decision With Panel	320	90%	90%	90%	90%	90%
	Decision Following Panel	60	*As resources permit*				
	Response to Approvable	60	*As resources permit*				
180 Day PMA Supplements	Substantive Interaction	90	95%	95%	95%	95%	95%
	Decision	180	95%	95%	95%	95%	95%
Real Time Supplements	Decision	90	95%	95%	95%	95%	95%
Pre-Submissions	Written Feedback	70 or 5d prior to mtg	1,530 (65%)	1,645 (70%)	1,765 (75%)	1,880 (80%)	1,950 (83%)
CLIA Waiver by Applications	Substantive Interaction	90	90%	90%	90%	90%	90%
	Dual CLIA/ 510(k)	180	90%	90%	90%	90%	90%
	Decision If No Panel	150	90%	90%	90%	90%	90%
	Decision With Panel	320	90%	90%	90%	90%	90%

Yellow highlight = new or changed goal

Program Highlights

Program Highlights

- Pre-Submission Process
- De Novo
- IT Enhancements
- Patient Engagement
- Real World Evidence
- Digital Health
- Standards
- Third Party Review
- Quality Management

New Pre-Submission Process

Day 1	• Sponsor provides 3 or more proposed meeting dates
Day 15	• FDA completes RTA* and either accepts one of the sponsor's dates or provides 2 alternatives prior to day 75
Day 30	• FDA and sponsor should agree on meeting date
Day 40	• Manager contacts sponsor to resolve scheduling (if needed)
Day 70	• Or 5 days ahead of scheduled meeting, FDA provides written feedback

FDA to publish guidance with acceptance checklist by FY19

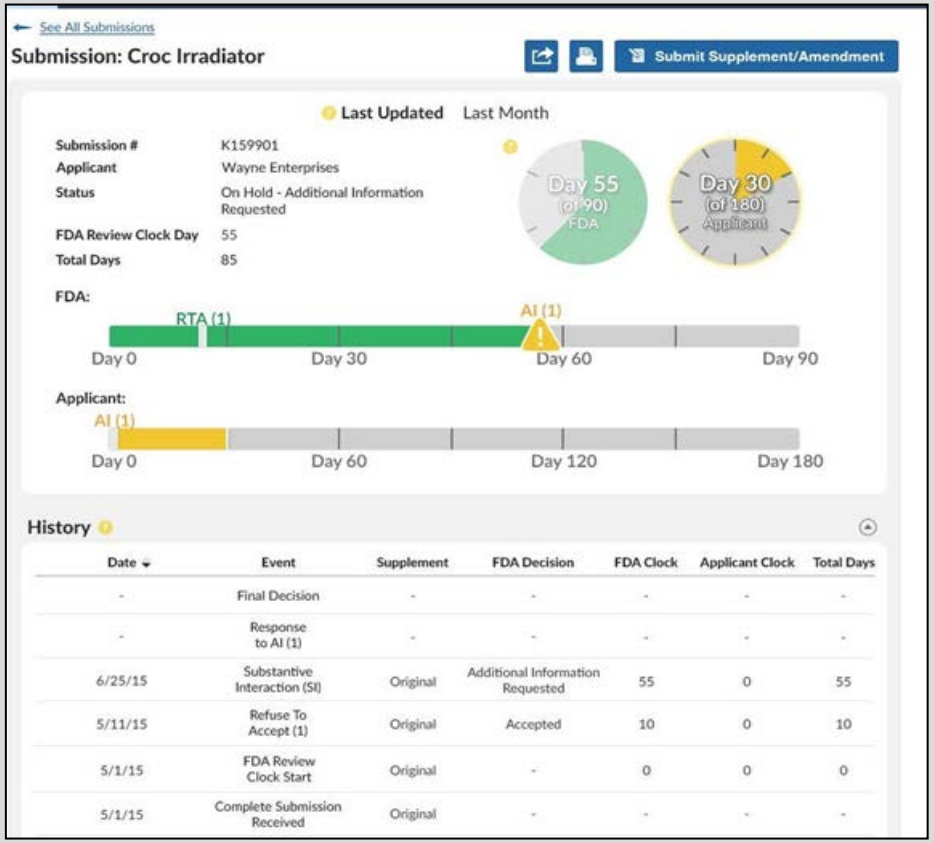
De Novo

- **Significant improvements made in MDUFA III without targeted additional resources**
  - Review times decreased
  - Number of submissions increased
- **Additional resources in MDUFA IV allocated to new De Novo performance goal**

IT Enhancements

- **Develop electronic submission templates**
  - Guided premarket submission preparation tool for industry
  - Improve submission quality
  - Help industry prepare complete premarket submissions
- **Develop smart review templates**
  - Create greater consistency in premarket reviews
- **Develop electronic dashboard to provide industry with near real-time submission status**

Industry Dashboard Prototype



Patient Engagement

- **Develop in-house expertise for review**
  - patient preference information (PPI)
  - patient reported outcomes (PROs)
- **Public workshops**
- **Improve regulatory predictability of PROs**
  - Voluntary
  - Outline a flexible framework for PRO validation
  - Develop model for “bridging studies” to make efficient use of existing PROs

Real World Evidence

- **Support the National Evaluation System for health Technology (NEST)**
  - FDA to determine usability of RWE for:
    - Expanded indications for use
    - New clearances/approvals
    - Improved malfunction reporting
  - Independent assessment to determine appropriate use of RWE for informing premarket decision-making
- **Streamline Medical Device Reporting**
  - Quarterly summary reporting of malfunctions for most/all product codes
    - including Class III and Class II implantable devices
  - FDA to maintain a list of eligible product codes on website

Digital Health

- **Establish Central Digital Health (DH) Unit**
  - Assist with digital health technologies in premarket review
- **Explore premarket pathways**
  - software as/in a medical device
  - account for RWE and international harmonization efforts

Consensus Standards

- **Establish Accreditation Scheme**
  - For Conformity Assessment of FDA-recognized consensus standards
  - Accrediting Bodies will accredit test labs according to specific FDA-recognized consensus standards
  - FDA will rely on testing conducted by an accredited lab in premarket reviews

Third Party Review

- **Establish plan to eliminate routine re-review**
- **Train 3rd parties**
  - Access to redacted memos
  - Convey changes in expectations for device types
- **Issue guidance on accreditation**
  - accreditation, reaccreditation, suspension, and withdrawal of accreditation

Quality Management

- **Establish a dedicated Quality Management (QM) Unit**
  - foster greater quality, consistency, and effectiveness in premarket review processes
- **Perform routine program audits to facilitate process improvements**

Summary

1. We reviewed the history of user fees for medical devices, including the chronology leading up to MDUFA IV
2. We learned what types of submissions and activities are subject to medical device user fees
3. We reviewed the user fee performance goals
4. We summarized the key program areas addressed by the MDUFA IV user fees

Industry Education: Three Resources for You

1. **CDRH Learn: Multi-Media Industry Education**
   - over 125 modules
   - videos, audio recordings, power point presentations, software-based "how to" modules
   - mobile-friendly: access CDRH Learn on your portable devices

   www.fda.gov/Training/CDRHLearn

2. **Device Advice: Text-Based Education**
   - comprehensive regulatory information on premarket and postmarket topics

   www.fda.gov/MedicalDevices/DeviceAdvice

3. **Division of Industry and Consumer Education (DICE)**
   - Contact DICE if you have a question
   - Email: **DICE@fda.hhs.gov**
   - Phone: 1(800) 638-2041 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
   - Web: **www.fda.gov/DICE**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