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

Elias Mallis
Director, Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration
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

<table>
<thead>
<tr>
<th>Law</th>
<th>Years</th>
<th>Key Provisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDUFMA (MDUFA I)</td>
<td>FY03 - FY07</td>
<td>provided resources to support premarket review</td>
</tr>
<tr>
<td>MDUFA II</td>
<td>FY08 - FY12</td>
<td>added more aggressive performance goals</td>
</tr>
<tr>
<td>MDUFA III</td>
<td>FY13 - FY17</td>
<td>increased resources with different performance goal structure</td>
</tr>
</tbody>
</table>

**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

• Federal Register Notice – Medical Device User Fee Rates for FY18
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

<table>
<thead>
<tr>
<th></th>
<th>MDUFA III</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th>MDUFA IV</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>FY13</td>
<td>FY14</td>
<td>FY15</td>
<td>FYF16</td>
<td>FY17</td>
<td>FY18</td>
<td>FY19</td>
<td>FY20</td>
<td>FY21</td>
<td>FY22</td>
<td></td>
</tr>
<tr>
<td>Goal</td>
<td>135</td>
<td>135</td>
<td>130</td>
<td>130</td>
<td>124</td>
<td>124</td>
<td>120</td>
<td>116</td>
<td>112</td>
<td>108</td>
<td></td>
</tr>
</tbody>
</table>

### PMA 3-Year Average Total Time to Decision

<table>
<thead>
<tr>
<th></th>
<th>MDUFA III</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th>MDUFA IV</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>FY11-</td>
<td>FY12-</td>
<td>FY13-</td>
<td>FY14-</td>
<td>FY15-</td>
<td>FY16-</td>
<td>FY17-</td>
<td>FY18-</td>
<td>FY19-</td>
<td>FY20-</td>
<td>FY21-</td>
</tr>
<tr>
<td></td>
<td>FY13</td>
<td>FY14</td>
<td>FY15</td>
<td>FYF16</td>
<td>FY17</td>
<td>FY18</td>
<td>FY19</td>
<td>FY20</td>
<td>FY21</td>
<td>FY22</td>
<td></td>
</tr>
<tr>
<td>Goal</td>
<td>395</td>
<td>395</td>
<td>390</td>
<td>390</td>
<td>385</td>
<td>320</td>
<td>315</td>
<td>310</td>
<td>300</td>
<td>290</td>
<td></td>
</tr>
</tbody>
</table>
### Summary of Performance Goals

<table>
<thead>
<tr>
<th>Submission Type</th>
<th>Action</th>
<th>FDA Review Days</th>
<th>Percent of Submissions to Meet FDA Days</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>FY18</td>
</tr>
<tr>
<td>510(k)s</td>
<td>Substantive Interaction</td>
<td>60</td>
<td>95%</td>
</tr>
<tr>
<td></td>
<td>Decision</td>
<td>90</td>
<td>95%</td>
</tr>
<tr>
<td>De Novos</td>
<td>Decision</td>
<td>150</td>
<td>50%</td>
</tr>
<tr>
<td>Original PMAs and Panel Track Supplements</td>
<td>Substantive Interaction</td>
<td>90</td>
<td>95%</td>
</tr>
<tr>
<td></td>
<td>Decision If No Panel</td>
<td>180</td>
<td>90%</td>
</tr>
<tr>
<td></td>
<td>Decision With Panel</td>
<td>320</td>
<td>90%</td>
</tr>
<tr>
<td></td>
<td>Decision Following Panel</td>
<td>60</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Response to Approvable</td>
<td>60</td>
<td></td>
</tr>
<tr>
<td>180 Day PMA Supplements</td>
<td>Substantive Interaction</td>
<td>90</td>
<td>95%</td>
</tr>
<tr>
<td></td>
<td>Decision</td>
<td>180</td>
<td>95%</td>
</tr>
<tr>
<td>Real Time Supplements</td>
<td>Decision</td>
<td>90</td>
<td>95%</td>
</tr>
<tr>
<td>Pre-Submissions</td>
<td>Written Feedback</td>
<td>70 or 5d prior to mtg</td>
<td>1,530 (65%)</td>
</tr>
<tr>
<td>CLIA Waiver by Applications</td>
<td>Substantive Interaction</td>
<td>90</td>
<td>90%</td>
</tr>
<tr>
<td></td>
<td>Dual CLIA/510(k)</td>
<td>180</td>
<td>90%</td>
</tr>
<tr>
<td></td>
<td>Decision If No Panel</td>
<td>150</td>
<td>90%</td>
</tr>
<tr>
<td></td>
<td>Decision With Panel</td>
<td>320</td>
<td>90%</td>
</tr>
</tbody>
</table>

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
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-4:30 pm EST)
   - Web: www.fda.gov/DICE