Medical Device User Fee Act (MDUFA) III Implementation

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Outline

• What we agreed to in the Commitment Letter
• Current status of implementing the Commitment Letter
How did we get from MDUFA I to MDUFA III?

• MDUFMA (MDUFA I) (FY 03- FY 07) - Enacted in 2002 to provide additional resources to an under resourced medical device program
• MDUFA II (FY 08- FY 12) - reauthorized in 2007 but with more aggressive performance goals
• MDUFA III (FY 13- FY 17) - reauthorized in 2012 with different performance goal structure and increased resources. Effective Oct. 1, 2012.
New Law
FDA Safety and Innovation Act (FDASIA)

• FDASIA includes:
  – 3 user fee programs:
    • Medical Devices (MDUFA)
    • Prescription Drugs (PDUFA)
    • Generic Drugs (GDUFA)
  – Many other provisions beyond user fees for FDA such as de novo pathway, IDE program and our post-market surveillance study (522) program. These provisions became effective on July 9th, 2012
MDUFA III Negotiations

- From January, 2011 through February 2012, FDA held discussions with the following industry representatives:
  - Advanced Medical Technology Association (AdvaMed)
  - Medical Device Manufacturers Association (MDMA)
  - Medical Imaging Technology Alliance (MITA), a subsidiary of the National Electronics Manufacturing Association (NEMA)
  - American Clinical Laboratory Association (ACLA)

- FDA also met monthly with patient and consumer advocacy representatives during negotiation period

- Detailed minutes of meetings were posted on the FDA web site http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm236902.htm
A Successful Result

The agreement reflects a careful balance between FDA commitments on review goals and process enhancements and Industry user fee funding to provide more timely access to safe and effective devices.
A Successful Result

- $595 million (plus inflation adjustment) over 5 years
- Process improvements and new/updated policies to enhance predictability, consistency, transparency, efficiency, and timeliness
- Improvements to infrastructure, including more FDA staff and managers
- Improvements to FDA review goals (i.e., number of days a submission is under FDA review)
- New shared outcome goals for which both Industry and FDA are responsible decisions
Key Features of the Commitment Letter
Process and Policy Improvements

- Pre-Submissions
- Submission Acceptance Criteria
- Interactive Review
- Substantial Interaction
- Guidance Development
- Third Party Review
- Patient Safety and Risk Tolerance
- Low Risk Medical Device Exemptions
- Emerging Diagnostics
Process and Policy Improvements

• Pre-Submission Process – A more structured approach to clarify product-specific requirements for IDEs, 510(k)s and PMAs prior to submission of an application
  – New “pre-submission” request from applicant
  – Documentation and guidelines designed to improve predictability and consistency
  – Improvements to be done within existing resource levels
  – Draft guidance has been issued

→ The Pre-Submission Program and Meetings with FDA Staff – http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm

This is an expansion of the former pre-IDE program.
Process and Policy Improvements

• Submission Acceptance Criteria – Improved “Refuse to Accept” (RTA) checklist of objective criteria for screening out 510(k) and PMA submissions that lack basic requirements
  – If a submission receives a RTA, the submission is not accepted and the review clock does not start until FDA receives a revised submission that meets required elements.
  – Draft guidance has been issued
    ➔ Refuse to Accept Policy for 510(k)s –
    ➔ Acceptance and Filing Review for PMAs –
Process and Policy Improvements

• The Interactive Review process is designed to help accomplish the following:
  – improve the interaction between the FDA review staff and the applicant during the review process;
  – prevent unnecessary delays in the completion of the review, thus reducing the overall time to market;
  – ensure that FDA’s concerns are clearly communicated to the applicant during the review process, as appropriate;
  – minimize the number of review cycles; and
  – minimize the number of review questions conveyed through deficiency letters.
• Interactive Review has no start/stop impact on the review clock.
Process and Policy Improvements

• Substantive Interaction – FDA will communicate to the applicant one of the following:
  – FDA will continue to resolve any outstanding deficiencies via Interactive Review; or
  – FDA has identified deficiencies that warrant placing the submission on hold.

• Guidance Document Development
  – Improved process for developing, tracking, and updating guidance
  – Publication of priority list of topics for development
  – More structured approach to gathering stakeholder input

• Third-Party Review
  – FDA will continue to support the third party review program and will work to strengthen and improve the current program while also establishing new procedures to improve transparency.
  – FDASIA – FDA will publish criteria for re-accreditation
Process and Policy Improvements

• Patient Safety and Risk Tolerance
  – FDA will implement the final guidance on factors to consider when making benefit-risk determinations
  – Final guidance has been issued
    – Commitment to meet with patient groups to better understand patient perspective
Process and Policy Improvements

• Low Risk Medical Device Exemptions
  – In FY 2013, FDA will propose additional low risk medical devices to be exempted
  – Within two years of that proposal, FDA intends to issue final rule exempting additional low risk devices from premarket notification

• Emerging Diagnostics
  – FDA will work with industry to develop a transitional In Vitro Diagnostics approach for the regulation of emerging diagnostics
Updated Quantitative Goals

• Simplified 1-Tier Structure
  – FDA review goals will have a simplified 1-Tier structure with a high percentage target for all submissions
  – Focuses on substantive interactions as interim milestones, based on best practices; the substantive interaction milestone is new

• No Submission Left Behind
  – For those submissions that miss the target number of review days, the “no submission left behind” feature improves transparency and accountability
    ▪ Communication with applicant shortly after goal is missed
    ▪ Discussion of outstanding issues and timeline for resolving them

The overall approach will improve predictability and reduce the number of submissions that drag on far beyond the initial target deadline, which will help reduce total time to decision.
<table>
<thead>
<tr>
<th>Submission Type</th>
<th>2008-2012</th>
<th>MDUFA III (2013-2017) - all in FDA Days except Average Total Time</th>
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<tr>
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<td>MDUFA II</td>
<td>FY13</td>
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<tr>
<td>510(k)</td>
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<tr>
<td>Tier 1</td>
<td>90% in 90 days</td>
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<td>Tier 2</td>
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<td>Average Total Time</td>
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<td>180 Day PMA Supplements</td>
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<tr>
<td>Tier 1</td>
<td>85% in 180 days</td>
<td>85% in 180 days</td>
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<td>Tier 2</td>
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<td>Interaction</td>
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<td>Original PMAs &amp; Panel Track Supplements</td>
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<tr>
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<td>No Panel - 70% in 180 days</td>
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<td>With Panel - 50% in 295 days</td>
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<td>Expedited PMAs</td>
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<td>Real Time PMA Supplements</td>
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<td>Tier 1</td>
<td>80% in 60 days</td>
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<tr>
<td>Tier 2</td>
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<tr>
<td>CLIA - with panel</td>
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Infrastructure Improvements

• Scientific and Regulatory Review Capacity
  – Reduction of reviewer-to-manager ratio
  – Staffing increases
  – Benchmark best practices for employee retention

• Training
  – Manager training
  – Reviewer certification program
  – MDUFA III training
Other Provisions

• Independent Assessment of Review Process
  – FDA will hire an independent consultant to conduct an evaluation of the device review process and make recommendations
  – FDA will develop a corrective action and implementation plan
    ▪ Incorporate relevant findings into a Good Review Management Practices guidance

• Performance Reports
  – As in MDUFA II, FDA will meet with Industry quarterly to present data, discuss progress toward meeting goals, etc.
  – Reports will include more information (some quarterly, some annually)
  – Reporting of data is more granular to allow for identification of issues common to multiple submissions that are leading to delays in decisions
Highlights of Legislative Language Supporting the Commitments
Elimination of Exemptions for Registration Fees

• All registered medical device establishments are required to pay the annual registration fee, regardless of establishment type or activities conducted.

• FDA estimates that this will increase the base of establishments paying registration fees from approximately 16,000 to approximately 22,000.

• A letter went out to Industry in August –

  ➔ Medical Device Establishment Registration and Listing - Notice of Changes for FY 2013
  [Link](http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm314844.htm?source=govdelivery)
Electronic Copy Provision

• Statutory language includes a requirement for applicants to provide an electronic copy with any pre-submission or submissions for devices

• Implementation of this requirement would occur only following the issuance of final guidance providing standards for such electronic copy and criteria for waivers of and exemptions from this requirement.
  – Draft guidance has been issued

  → Draft Guidance - eCopy Program for Medical Device Submissions
Implementation of MDUFA III
Hiring

• 32 pre-hired employees using reserved MDUFA II funding

• Pre-hires filled the newly created manager positions in the ODE and OIVD reorganization

• FDA has also hired a “substantial” number of the 65 allotted full-time equivalent (FTE) employees allocated as part of the MDUFA III funding for fiscal year 2013.
Required MIII Guidance

Finalization will occur over the coming months

- Refuse to Accept Policy for 510(k)s, draft
- Acceptance and Filing Review for Premarket Approval Applications, draft
- eCopy Program draft
Required MIII Guidance

• Refuse to accept policy will begin on Jan. 1, 2013 (includes e-Copy policy)
Other MIII Guidance

• Pre-Submission Interactions, *draft*
• Types of Communication During the Review of Medical Device Submissions, *in-process*
• PMAs: Effect on FDA Review Clock and Goals, *final*
• 510(k) Submissions: Effect on FDA Review Clock and Goals, *final*
• PMAs: User Fees and Refunds, *in-process*
• 510(k) Submissions: User Fees and Refunds, *in-process*
Training

• **MDUFA III Training**
  - 16 hours of mandatory training is required for all review staff.

• **Manager Training**
  - Leadership Enhancement and Development Program for Managers and Supervisors (CDRH LEAD Program)

• **Reviewer Training**
  - Reviewer Certification Program (RCP)
Transition Period

• **RTA** checklists can be filled in and included in applications

• **e-copy**: Specific technical standards are needed – free eSubmitter tool available to create an e-copy that meets the new technical standards

• **Q submissions** – all new pre-submissions and meeting requests will be assigned a “Q” number
Independent Assessment
Phase 1

• FDA will award the contract by 2\textsuperscript{nd} Quarter FY13.
• Findings on high-priority recommendations published within six months of award.
• Final comprehensive findings and recommendations published within 1 year of contract award.
• Publish implementation plan within 6 months of receipt of each set of recommendations
Decisions Rendered via Auto-Emails

- MDUFA III IT initiatives include auto-emails in lieu of manually-generated correspondence.
- Auto-emails apply to the following decisions:
  - Acceptance Review
    - Accept – email
    - Not Accept – email with RTA checklist attached
  - FILE decision (Not File requires letter)
  - Substantive Interaction decision to Proceed Interactively (all other SI decisions require letters)
  - Missed MDUFA Decision.
Substantive Interaction

SI ≠ IR

• Substantive Interaction Options: (1) put submission on hold with deficiency letter; or (2) inform the sponsor via an auto-email that we will resolve outstanding deficiencies via IR.

• Example Auto-email language - “FDA has completed a substantive review of your submission and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.”
Interactive Review (IR)

- A process of requesting additional information from the sponsor while the submission is under review.
- IR before SI is discretionary.
- IR after SI is required.
- IR requests do not impact the review clock.
- With rare exceptions (e.g., emails that exceed 50MB), all IR responses from sponsors can be accepted via email and added to the official review record.
DocMan

- DocMan = CDRH’s **Document Manager**.

- It is an electronic repository that will be used to manage FDA review records (review memos, checklists, correspondence, emails, approval packages, etc.).
Benefits of DocMan

• IR emails to and from the sponsor will cc: an unique DocMan email address (e.g., K130001@docs.fda.gov) to allow for a copy of the email to go into the DocMan repository for that submission.

• Few items need to be printed.

• Complements new auto-email processes.

• Complements new digital signature policy for memos, checklists, and correspondence.
Digital Signatures

Correspondence will be digitally signed and electronically dated.
MDUFA III Performance
Resources

- MDUFA III internet page (http://www.fda.gov/mdufa)