MEDICAL DEVICE USER FEE AMENDMENTS (MDUFA) REAUTHORIZATION

FDA Perspective

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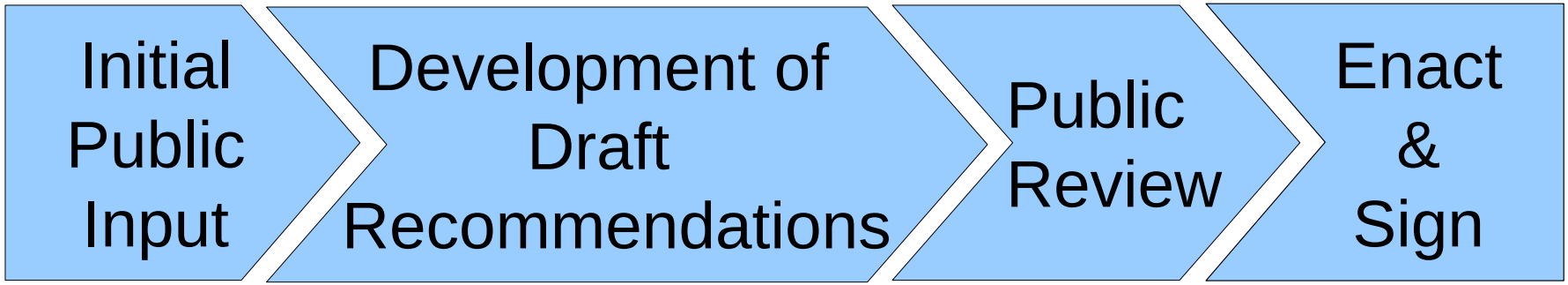
Overview

- Process for developing recommendations to Congress
- Key features of the draft recommendations
- Questions about the draft recommendations

Overview of Process for Developing Recommendations to Congress

Medical Device User Fee Program Reauthorization Process



- Initial Public meeting √
- 30-day comment period √
- Post comments on FDA web site √

- Negotiations with regulated industry √
- Publication of meeting summaries √
- Monthly meetings with stakeholders √
- HHS and OMB review √

- Present draft to Congressional committees √
- Publish draft in Federal Register √
- Public meeting √
- 30-day comment period
- FDA revises as needed
- HHS Secretary transmits to Congress

Development of Recommendations

- 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 are posted on the FDA web site

Patient, Healthcare, & Consumer Advocacy Representatives

- The AIDS Institute
- Alliance for Aging Research
- American Association for Cancer Research
- Juvenile Diabetes Research Foundation
- National Alliance on Mental Illness
- National Health Council
- National Multiple Sclerosis Society
- National Organization for Rare Disorders
- Parkinson's Action Network
- Spina Bifida Association
StopAfib.org
- United Spinal Association
- WomenHeart
- American Academy of Pediatrics
- American Association of Neurological Surgeons
- American Association of Orthopaedic Surgeons/American Academy of Orthopaedic Surgeons
- American Hospital Association
- American Society of Cataract and Refractive Surgery
- American Society for Radiation Oncology
- Association of Black Cardiologists
- Heart Rhythm Society
- Consumer Federation of America
- Consumers Union
- National Research Center for Women & Families
- National Women's Health Network
- Society for Women's Health Research
- Union of Concerned Scientists

Recap of Key Negotiation Milestones

2011	JAN	FEB	MAR	APR
	Kickoff and analysis of program issues			FDA Initial Proposal
	MAY	JUN	JUL	AUG
		Industry's Initial Proposal	FDA Plan to Mitigate Uncertainties	Industry's Detailed Proposal	Counter-proposals…
	SEP	OCT	NOV	DEC
	… and more counter-proposals…	Initial Draft Goals	Financial discussions…	
2012	JAN	FEB	MAR	APR
	… Agreement in Principle	Draft Recommendations	Public Comment Period	

A Successful Result

- The agreement reflects a careful balance between what FDA was willing to commit to accomplish within the user fee amounts Industry was willing to pay
  - $595 million (plus inflation adjustment) over 5 years
  - Process improvements to enhance transparency, consistency, predictability, and productivity
- The provisions of the agreement are intended to provide more timely access to safe and effective devices
  - Improvements to FDA review goals
  - New shared outcome goals for reducing average total time to decisions for Pre-Market Approval (PMA) and Pre-Market Notification (a.k.a., “510(k)”) submissions

Key Features of the Draft Recommendations

1. Draft Commitment Letter

2. Proposed Legislative Language

1. Key Features of the Draft Commitment Letter

"FDA and the industry are committed to protecting and promoting public health by providing timely access to safe and effective medical devices. Nothing in this letter precludes the Agency from protecting the public health by exercising its authority to provide a reasonable assurance of the safety and effectiveness of medical devices. Both FDA and the industry are committed to the spirit and intent of the goals described in this letter."

- Process Improvements
- Review Performance Goals
- Shared Outcome Goals
- Infrastructure and Other Provisions

Improved 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

Process 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 submission received RTA, review clock does not start until FDA receives a revised submission that meets acceptance criteria
- **Interactive Review**
  - Reaffirms commitment to FDA/sponsor interactions
- **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

Process Improvements

- **Third-Party Review**
  - FDA supports reauthorization of existing program, plans to make improvements through standard operating procedures
  - More ambitious improvements to the program were considered but not pursued after discussion of resource implications

- **Patient Safety and Risk Tolerance**
  - Guidance on factors to consider when making benefit-risk determinations
  - Commitment to meet with patient groups to better understand patient perspective

Process Improvements

- **Low Risk Medical Device Exemptions**
  - In FY 2013, FDA will propose additional low risk medical devices to be exempt
  - 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

Quantitative Review Performance Goals

- FDA review goals will have a simplified 1-Tier structure with a high percentage target for all submissions
  - Focuses on initial and substantive interactions as interim milestones, based on best practices
  - 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
  - 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

Shared Outcome Goals for Total Time to Decision

- Total time to decision is an outcome of the review process that is a shared responsibility among FDA and Industry (hence “shared outcome goal”)
- Specific targets set for average total time in FY13, and reductions from that point
- To limit the effect of outliers, the metric uses a “trimmed mean” that excludes extreme values
  - Single year average excluding the highest 2% and lowest 2% for 510(k)s
  - Three year rolling average excluding the highest 5% and lowest 5% for PMAs
- The cohort is “closed” when less than 100% of decisions are completed to allow the determination of goal attainment earlier
  - Single-year 510(k) cohort “closed” when 99% of the accepted submissions have reached a decision
  - Three-year PMA cohort “closed” when 95% of the applications have reached a decision

Summary of Performance Goals per 02/17/2012 Agreement

Submission Type		2007	2008-2012	2013-2017 (01/31/2012 Agreement) - all in FDA Days except Average Total Time				
		End of MDUFMA I	MDUFA II	FY13	FY14	FY15	FY16	FY17
510(k)	Tier 1	80% in 90 days	90% in 90 days	91% in 90 days	93% in 90 days	95% in 90 days	95% in 90 days	95% in 90 days
	Tier 2	N.A.	98% in 150 days					
	Cycle	90% in 75 days	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
	Interaction	N.A.	N.A.	65% in 60 days	75% in 60 days	85% in 60 days	95% in 60 days	95% in 60 days
	Average Total Time	N.A.	N.A.	135 days	135 days	130 days	130 days	124 days
180 Day PMA Supplements	Tier 1	90% in 180 days	85% in 180 days	85% in 180 days	90% in 180 days	90% in 180 days	95% in 180 days	95% in 180 days
	Tier 2	N.A.	95% in 210 days					
	Cycle	90% in 120 days	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
	Interaction	N.A.	N.A.	65% in 90 days	75% in 90 days	85% in 90 days	95% in 90 days	95% in 90 days
Original PMAs & Panel Track Supplements		Tier 1 - 50% in 180 days	Tier 1 - 60% in 180 days	No Panel - 70% in 180 days	No Panel - 80% in 180 days	No Panel - 80% in 180 days	No Panel - 90% in 180 days	No Panel - 90% in 180 days
		Tier 2 - 90% in 320 days	Tier 2 - 90% in 295 days	With Panel - 50% in 320 days	With Panel - 70% in 320 days	With Panel - 80% in 320 days	With Panel - 80% in 320 days	With Panel - 90% in 320 days
	Cycle	75% in 150 days	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
	Interaction	N.A.	N.A.	65% in 90 days	75% in 90 days	85% in 90 days	95% in 90 days	95% in 90 days
	Average Total Time	N.A.	N.A.	395 days	395 days	390 days	390 days	385 days
Expedited PMAs	Tier 1	90% in 300 days	50% in 180 days	Included with "Original PMAs"	Included with "Original PMAs"	Included with "Original PMAs"	Included with "Original PMAs"	Included with "Original PMAs"
	Tier 2	N.A.	90% in 280 days					
	Cycle	70% in 120 days	N.A.					
Real Time PMA Supplements	Tier 1	N.A.	80% in 60 days	90% in 90 days	90% in 90 days	95% in 90 days	95% in 90 days	95% in 90 days
	Tier 2	N.A.	90% in 90 days					
CLIA Waiver Applications	Dual CLIA/ 510(k)	N.A.	N.A.	90% in 210 days	90% in 210 days	90% in 210 days	90% in 210 days	90% in 210 days
	CLIA - no panel	N.A.	N.A.	95% in 180 days	95% in 180 days	95% in 180 days	95% in 180 days	95% in 180 days
	Clia - with panel	N.A.	N.A.	95% in 330 days	95% in 330 days	95% in 330 days	95% in 330 days	95% in 330 days

Infrastructure

- Scientific and Regulatory Review Capacity
  - Reduction of reviewer-to-manager ratio
  - Benchmark best practices for employee retention
- Training
  - Management training
  - Reviewer certification program
  - MDUFA III training
- Tracking System
  - FDA will continue to improve IT systems to support future capability for real-time status of submissions

Other Provisions

- Independent Assessment of Review Process
  - FDA hires a consultant to conduct an evaluation of the device review process, make recommendations
  - FDA develops a corrective action and implementation plan
    - Incorporates relevant findings into a Good Review Management Practices guidance
- Performance Reports
  - As in MDUFA II, FDA meets 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 improve transparency and diagnostic value
- Discretionary Waiver
  - Submissions granted the waiver are not part of goal cohort
  - Discretionary waiver authority expires at the end of MDUFA III

2. Highlights of Proposed Legislative Language

Statutory Fee Structure

- Statutory language has been updated to reflect the dates of the MDUFA III period
- Premarket notification submissions (510(k)s) will be assessed a fee equal to 2% of the premarket application (PMA) fee, up from 1.84% during MDUFA II
- Base fee amounts for premarket application and establishment registration fees are outlined in statutory language
- Total revenue amounts for each fiscal year are outlined in the statutory language
- Annual fee setting has been updated to include an adjustment to total revenue amounts and base fee amounts to account for inflation and an adjustment to the establishment registration base fees, as needed, to generate the total adjusted revenue amounts

Elimination of Exemptions for Registration Fees

- Industry proposed and FDA agreed that all establishments required to register also should be subject to a registration fee
  - FDA estimates that this will increase the base of establishments paying registration fees from approximately 16,000 to approximately 22,000

Fee Waiver or Reduction Authority

- Proposed statutory language includes a provision for the Secretary, at the Secretary's sole discretion, to grant a waiver or reduction of fees if the Secretary finds that such waiver or reduction is in the interest of public health.
  - If FDA modifies its current policy of enforcement discretion regarding the regulation of laboratory developed tests (LDTs), FDA intends to grant waivers for the affected LDT submissions and manufacturers
  - Would not be granted for current LDT manufacturers or those who voluntarily register and submit during MDUFA III
  - Provision sunsets at the end of MDUFA III

Updated Trigger & Offset Provisions

- Proposed statutory language includes an update to the appropriations trigger and the spending trigger to FY 2009 levels
- Technical updates to offset provision
  - Less likelihood of excess collections due to new adjustment provision
- Technical amendments regarding relationship between appropriations and user fee collections (implemented across user fee programs)

Electronic Copy Provision

- Proposed 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.

Streamlined Hiring Authority

- FDA requests streamlined hiring authority for the first three years of MDUFA III to facilitate the steep ramp-up in hiring to accomplish the ambitious goals agreed to in the commitment letter