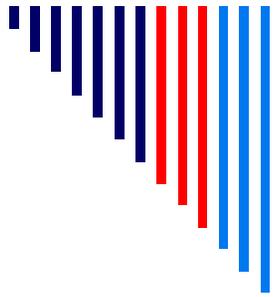
A decorative graphic on the left side of the slide consisting of a series of vertical bars of varying heights and colors (dark blue, red, light blue) that create a stepped, staircase-like effect.

# **Medical Device User Fee and Modernization Act (MDUFMA II)**

## **Legislative Recommendations**

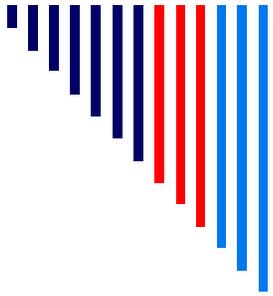
April 30, 2007



# Purpose



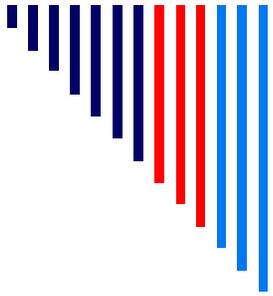
- Background
- Legislative Recommendations
- Next Steps



# Objectives of MDUFMA I



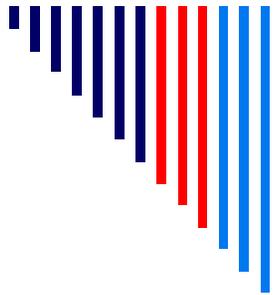
- Sustainable review program with:
  - Increased predictability in review times
  - Increased timeliness in review process
- Overall Objective: Get safe and effective devices to patients and healthcare professionals more quickly



# FDA Standards Unchanged



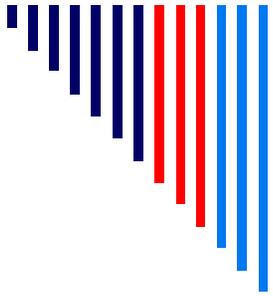
- MDUFMA provides FDA with additional resources to make improvements to the ***review process***
- The ***review standards*** do not change



# Overview of MDUFMA I as Amended by MDUFSA



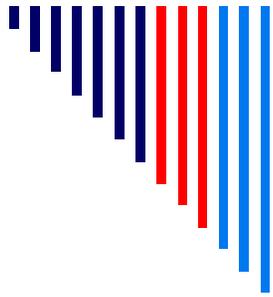
- Currently 83% of funding comes from appropriations and 17% from fees
  - Appropriations increased 3.5% on average annually
  - Fees increased 8.5% in FYs 06-07
- Small Businesses
  - Waivers --  $\leq$  \$30 million (1<sup>st</sup> PMA/BLA)
  - Fee discounts --  $\leq$  \$100 million
- Other Waivers (e.g., HDE, pediatrics)
- Triggers
- Performance goals: 77 quantitative and 8 qualitative
- Third party inspection program
- Reprocessed single-use devices
- Office of Combination Products



# MDUFMA I vs MDUFMA II



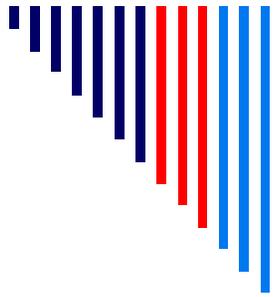
- MDUFMA I
  - Increase the size of the review program
  - Improve the timeliness of review
- MDUFMA II
  - Maintain a stable review program
  - Continued performance improvement
  - Fine tune the user fee program



# Key Challenges



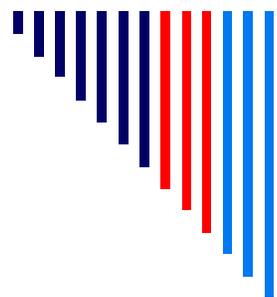
- Performance goals had unintended consequences
- Third party inspection program has not been a success
- FDA lacks predictable and stable user fee funding



# Key Goals for FDA



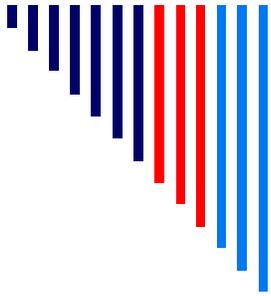
- Simplify the performance goal structure
- Make the third party program workable
- Provide adequate and predictable funding for FDA to maintain a stable device review program



# Recommendations for Legislation



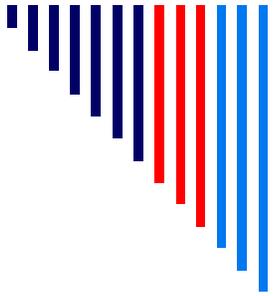
- Performance Goals
  - Quantitative Goals
  - Qualitative Goals
- Funding
  - User Fee Revenues
  - User Fee Structure
  - Small Business Fee Reductions
- Third Party Inspection Program



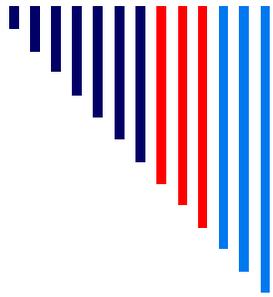
# Benefits to Public Health



- Patients and practitioners will have access to safe and effective medical devices more quickly
  - Continued improvement in device review times and greater transparency of the review process
- FDA will have the resources to maintain the cutting edge scientific expertise necessary to provide timely review and ensure the safety of the increasingly complex devices of tomorrow
  - Adequate and stable funding for FDA
- FDA can better focus its inspectional resources on higher risk devices
  - Enhance the third party inspection program



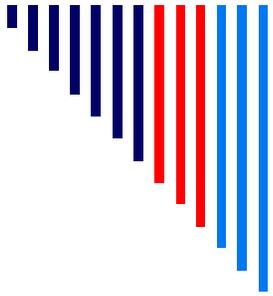
# Performance Goals



# Examples of Current Quantitative Goals



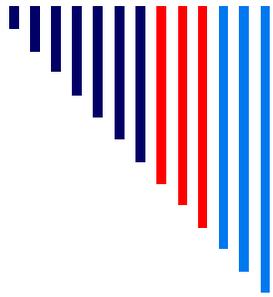
| Goals for PMAs, Panel-track PMA Supplements, and Premarket Reports |                                                                                                       | Review Time Goal | Performance Level |       |       |       |       |
|--------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|------------------|-------------------|-------|-------|-------|-------|
|                                                                    |                                                                                                       |                  | FY 03             | FY 04 | FY 05 | FY 06 | FY 07 |
| Decision                                                           | Make an "FDA decision"                                                                                | 320 days         | No Goal           |       |       | 80%   | 90%   |
| Cycle                                                              | Issue a "major deficiency" letter as the first action                                                 | 150 days         | No Goal           |       | 75%   | 80%   | 90%   |
|                                                                    | Issue all other first actions                                                                         | 180 days         | No Goal           |       | 75%   | 80%   | 90%   |
|                                                                    | Issue a "major deficiency" letter as the second or later action                                       | 120 days         | No Goal           |       | 75%   | 80%   | 90%   |
|                                                                    | Act on an amendment containing a complete response to a "major deficiency" or "not approvable" letter | 180 days         | No Goal           |       | 75%   | 80%   | 90%   |
|                                                                    | Act on an amendment containing a complete response to an "approvable" letter                          | 30 days          |                   |       | 90%   |       |       |



# Quantitative Goals



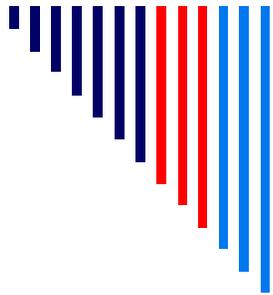
- Proposing continued improvements with current staffing levels
  
- Goals
  - Eliminate the cycle goals
  - Two-tiered decision goals
  - New goals for some application types



# Comparison of Quantitative Decision Goals in MDUFMA I and II



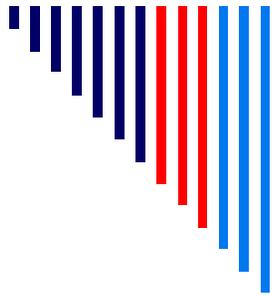
| MDUFMA I                                                            | MDUFMA II                                                                   |
|---------------------------------------------------------------------|-----------------------------------------------------------------------------|
| PMA Final Decision Goals                                            |                                                                             |
| 50% of PMAs and panel track PMA supplements in 180 days             | 60% of PMAs and panel track PMA supplements in 180 days                     |
| 90% of PMAs, panel-track supplements, premarket reports in 320 days | 90% of PMAs and panel track PMA supplements in 295 days                     |
| NA                                                                  | 50% of expedited PMAs and expedited panel track PMA supplements in 180 days |
| 90% of expedited PMAs in 300 days                                   | 90% of expedited PMAs and expedited panel track PMA supplements in 280 days |
| Modular PMA Goals                                                   |                                                                             |
| NA                                                                  | 75% of PMA modules in 90 days                                               |
| NA                                                                  | 90% of PMA modules in 120 days                                              |
| 510 (k) Goals                                                       |                                                                             |
| 80% of 510(k)s in 90 days                                           | 90% of 510(k)s in 90 days                                                   |
| NA                                                                  | 98% of 510(k)s in 150 days                                                  |



# Comparison of Quantitative Decision Goals in MDUFMA I and II, cont'd



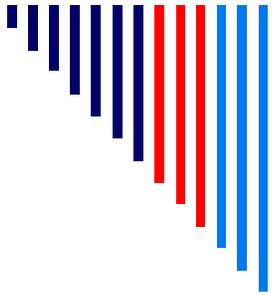
| MDUFMA I                                                              | MDUFMA II                                   |
|-----------------------------------------------------------------------|---------------------------------------------|
| 180-Day PMA Supplement                                                |                                             |
| 90% of 180-Day PMA supplements in 180 days                            | 85% of 180-Day PMA supplements in 180 days  |
|                                                                       | 95% of 180-Day PMA supplements in 210 days  |
| Real-Time PMA Supplements                                             |                                             |
| NA                                                                    | 80% of Real-Time PMA Supplements in 60 days |
|                                                                       | 90% of Real-Time PMA Supplements in 90 days |
| BLA Goals                                                             |                                             |
| 90% of BLAs in 10 months                                              | Same as MDUFMA I                            |
| 90% of BLA supplements in 10 months                                   |                                             |
| 90% of BLA resubmissions and BLA supplement resubmissions in 2 months |                                             |



# Qualitative Goals



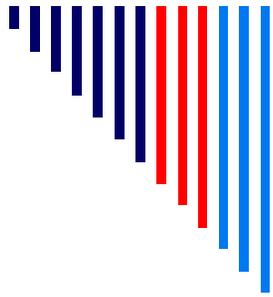
- Goals for:
  - Interactive review
  - Maintenance of performance
  - Guidance document development
  - Quarterly updates
  - Meetings
  - Reviewer training



## Qualitative Goals, cont'd



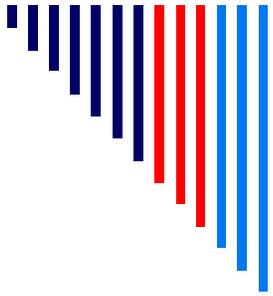
- Imaging Devices
  - Issue guidance on processes and procedures, including data that should be submitted, for review of imaging devices that use contrast agents and radiopharmaceuticals



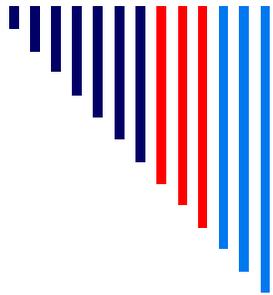
# Qualitative Goals, cont'd



- In Vitro Diagnostics
  - Issue new or revised guidance to improve review of laboratory tests—including IVDs that can address biothreats, pandemic influenza, and emerging infectious disease
  - Evaluate ways to combine 510(k) review with CLIA waiver process to speed access to diagnostic tests at point of care
  - Evaluate whether additional low risk IVDs could be exempted from premarket review
  - Conduct a program review to determine if FDA can provide advice on clinical studies earlier in the IVD development process



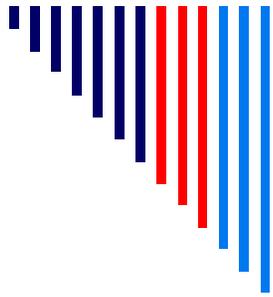
# Third Party Inspection Program



# Third Party Inspections in MDUFMA I



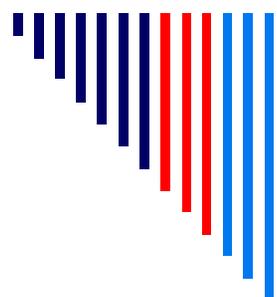
- Accredited Persons (APs) are firms trained by FDA to conduct biennial GMP inspections
- Strong protections against conflicts of interest
- Only firms with a good track record are eligible
- FDA can still inspect firms
- Allows FDA to better focus its inspectional resources based on risk



# Challenges on Third Party Program



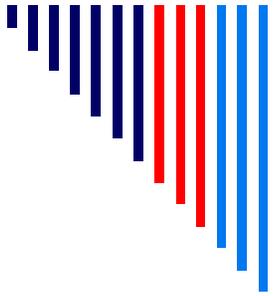
- Limited industry participation
  - 14 medical device firms have petitioned FDA to use an AP
  - 3 independent AP inspections completed
- Costly for FDA to operate
  - ~\$2.9 million already spent on establishing and operating the program
- Disincentives
  - Current petition process is cumbersome
  - Ability to use APs is limited



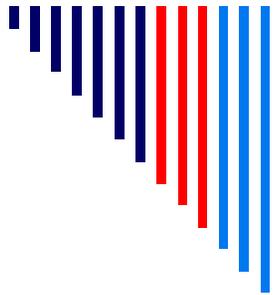
# Recommended Changes to the Program in MDUFMA II



- Streamline administrative burdens
  - Firms would provide FDA 30 day notice of their intent to use an AP rather than petitioning FDA for clearance to use an AP
- Expand participation
  - Firms may use an AP for an unlimited number of consecutive inspections without seeking a waiver, rather than only two consecutive inspections
  - FDA would continue to conduct “for cause” or follow-up inspections at our discretion
- Encourage industry to provide FDA with more data
  - Firms may voluntarily submit reports by third parties assessing conformance with appropriate international quality systems standards, such as ISO, which FDA would consider in setting our inspectional priorities



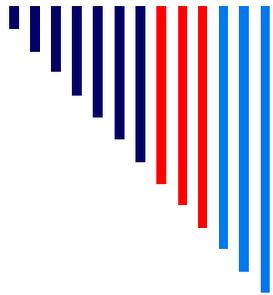
# Funding and Fee Structure



## Challenge—Keeping up with Costs



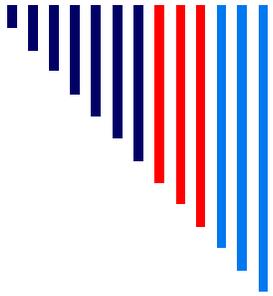
- Over the last 5 years the cost of an FTE at FDA has increased on average 5.8% annually
- The cost of the device review program is expected to increase on average 6.4% annually during the next 5 years—due largely to costs of the White Oak facility (7.8%, if include the cost of the move)



## Challenge—Keeping up with Costs



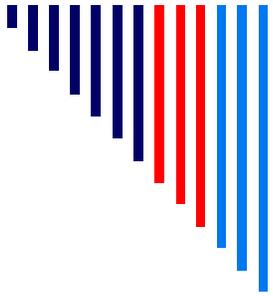
- Funding through appropriations and fee revenues is not keeping pace with the increase in costs
- We estimate that FDA will need \$1.249 billion in combined appropriation and user fee funding over the 5 years of MDUFMA II to maintain the current program



# MDUFMA II Funding



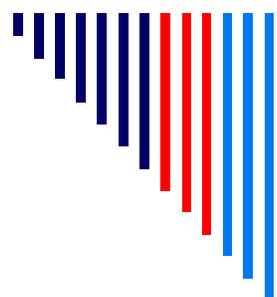
- Premised on appropriations for the device review program continuing to increase at 3.5% annually
- User fee expectation – \$287 million
- Over the course of MDUFMA II, 77% of funding would come from appropriations and 23% from fees



# MDUFMA I Fee Structure



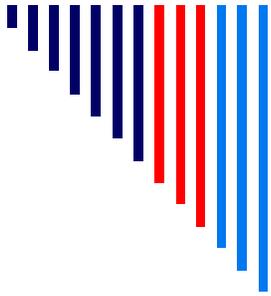
- User fee revenues derived solely from application fees and very volatile
- Fees for some, but not all, types of applications
- Fee revenues chronically short of expectations



# Recommended Fee Structure for MDUFMA II



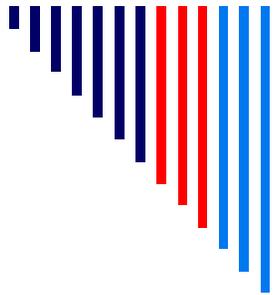
- Create new fees
  - New: Establishment registration fee
  - New: Fee for periodic reports (annual reports)
  - New: Fees for additional types of applications
  - Continued: All fees provided by MDUFMA, but at lower rates
- Also provide 5 years of predictable fee levels for industry



# Small Businesses



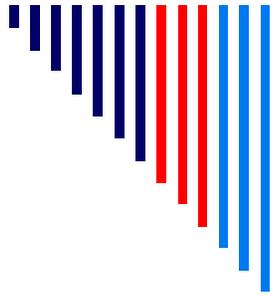
- Continue first time PMA waiver for SBs with  $\leq$  \$30 million in annual sales or receipts
- Greater fee discounts for SBs with  $\leq$  \$100 million in annual sales or receipts
  - Rates for PMAs and related supplements reduced from 38% to 25% of the full fee in MDUFMA II
  - Rates for 510(k)s reduced from 80% to 50% of the full fee in MDUFMA II
- Make it easier for foreign business entities to qualify as SBs



# Triggers



- The success of MDUFMA II depends on providing increasing funding to FDA from both appropriations and user fees to meet the agency's increasing costs
- The MDUFMA I trigger for appropriations would be extended through MDUFMA II



## Next Steps



- Public comment period closes on May 18
- FDA will review comments, modify its proposals as appropriate, and then submit its final legislative recommendations to Congress