FY 2003 PERFORMANCE REPORT TO CONGRESS

for the

Medical Device User Fee and Modernization Act of 2002

Food and Drug Administration
Department of Health and Human Services

Commissioner's Report

Twenty-first century technology is creating new medical devices at an unprecedented pace and has challenged FDA's ability to keep apace with timely review of safety and effectiveness, to ensure that patients have early access to new medical devices. Last year, Congress passed the Medical Device User Fee and Modernization Act (MDUFMA), providing the added resources needed to ensure that FDA can provide that rapid review. In return for these user fees, FDA is pursuing a comprehensive set of device review performance goals that will significantly improve the timeliness and predictability of FDA's review of new device applications. This report identifies what we expect to accomplish under MDUFMA and presents our accomplishments for the first year of MDUFMA.

MDUFMA authorizes FDA to do the following:

- Collect user fees for premarket reviews of medical device applications.
- Accredit persons (third-parties) to conduct establishment inspections, under carefully prescribed conditions.
- Require new regulations for reprocessed single-use devices, including the submission of additional data on devices now being reprocessed, and a new category of premarket submission, the premarket report.

FDA met or exceeded all of MDUFMA's FY 2003 commitments and initiative expectations. In addition, we published and developed guidances for industry and FDA staff, hired additional staff, and initiated outreach efforts to stakeholders. While this first year of the program was primarily one of transition, and we still have some building blocks to put in place, I am proud to say we are off to a great start.

As we implement MDUFMA, we are applying the best biomedical science and risk management. Determining whether products are safe and effective in the least costly and burdensome manner translates into lower costs for innovating and more new products for more patients. MDUFMA will help bring innovative, affordable products to the market quickly, without compromising product safety and efficacy and help FDA fulfill our increasingly complex public health mission.

Mark B. McClellan, M.D., Ph.D.
Commissioner of Food and Drugs

Executive Summary

On October 26, 2002, the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) was signed into law. MDUFMA amends the Federal Food, Drug, and Cosmetic Act to authorize FDA to collect user fees from manufacturers that submit certain applications to market medical devices. In exchange for this authority, MDUFMA requires that the FDA pursue a comprehensive set of review performance goals and commitments to improve the timeliness and predictability of medical device reviews.

FY 2003 Activities: MDUFMA's review performance goals recognize that FDA will need a two-year start-up period (FY 2003 through FY 2004) to hire and train new staff and construct review program infrastructures before it will be possible to make substantial progress in improving overall review performance. Consequently, most review performance goals do not go into effect until FY 2005. To gear up for the more ambitious MDUFMA performance goals of FY 2005 through FY 2007, FDA conducted the following activities:

- **Guidance and Procedural Development**. The Agency developed and published eleven guidance documents to assist industry in preparing high-quality applications that respond to all relevant statutory and regulatory requirements and to help ensure that FDA reviews of these applications are rapid, thorough, and efficient. Appendix F provides a complete list of these guidance documents published during FY 2003.
- **Public Notification**. The Agency developed and published *Federal Register* notices providing information on the implementation of MDUFMA. Appendix G provides a complete list of these *Federal Register* notices published during FY 2003.
- **Hiring and Management Initiatives**. The Agency has hired additional staff, including 67 in CDRH, bringing valuable expertise to the evaluation of medical devices.
- **Outreach and Education**. The Agency launched an Internet site to provide information about MDUFMA (e.g., legislation requirements, guidance documents, action dates, information on meetings) to the medical device industry and the public (www.fda.gov/oc/mdufma). In addition, to improve the exchange of information between the FDA and stakeholders, the Agency established an open docket (www.fda.gov/ohrms/dockets/dockets/02n0534/02n0534.htm) and scheduled a public stakeholder meeting for December 3, 2003.

FY 2003 Performance Goals and Commitments: FDA's performance during FY 2003 was consistent with MDUFMA's goals and expectations. Although the FY 2003 goals for PMAs and expedited PMAs did not go into effect (because the conditions necessary to trigger those goals did not occur), the Agency made good progress on the entire set of goals for FY 2003 and laying the groundwork for achieving the goals that go into effect in later years.

Future MDUFMA Activities: During FY 2004, FDA plans to expand these initial efforts through additional employee hiring, training, guidance development, electronic tracking/review system expansion, and outreach. These improvements are intended to ensure the Agency meets upcoming MDUFMA performance goals and commitments. The Agency expects that implementation of MDUFMA will result in device products reaching the American public in a more timely and predictable manner without compromising standards of product safety and effectiveness.

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Introduction

On October 26, 2002, the Medical Device User Fee and Modernization Act (MDUFMA) was signed into law. MDUFMA amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) to authorize FDA to collect fees from companies that submit certain applications for marketing of medical devices. In return, MDUFMA requires FDA to pursue a comprehensive set of device review performance goals that will significantly improve the timeliness and predictability of FDA's review of new devices[1]. These performance goals were developed collaboratively and are defined in Department of Health and Human Services (DHHS) Secretary Thompson's November 14, 2002 letter to Congress.[2] Information about MDUFMA, including the text of the amendments and the performance goals and procedures, can be found at http://www.fda.gov/oc/mdufma.

MDUFMA requires the Secretary to submit two annual reports to Congress for each fiscal year during which fees are collected: 1) a performance report due within 60 days of the end of the fiscal year, and 2) a financial report due within 120 days of the end of the fiscal year. This document fulfills the first of these requirements for fiscal year 2003. FDA's authority to collect user fees under MDUFMA expires after five years.

[1] Section 738(g) of FD&C Act, as amended by MDUFMA. Except where noted, all statutory citations in this report are to the Federal Food, Drug, and Cosmetic Act, as amended by MDUFMA.

[2] DHHS Secretary Thompson submitted the required letter to Congress on November 14, 2002 (Congressional Record, November 19, 2002, p. S11549). For convenience, this report refers to this letter as "FDA's commitment letter." The complete text of the letter is provided in Appendix A.

Overview of MDUFMA

The Medical Device User Fee and Modernization Act (MDUFMA) was signed into law on October 26, 2002, amending the Federal Food, Drug, and Cosmetic Act to provide FDA important new responsibilities, resources, and challenges. The goal of MDUFMA is to better serve the public health by providing additional funds to FDA for "the process for the review of devices and the assurance of device safety and effectiveness so that statutorily mandated deadlines may be met." The user fees provided by MDUFMA, and the additional appropriations that go with the new law, will provide the following significant benefits:

- Safe and effective medical devices will reach patients more rapidly.
- Manufacturers will receive timely, high quality reviews with greater consistency.
- Resources will be provided to ensure that devices marketed in the United States continue to meet high standards for safety and effectiveness.

The majority of devices associated with MDUFMA are reviewed by the Center for Devices and Radiological Health (CDRH). However, a number of devices that are critical to ensuring the safety of human tissue products and the safety, purity and potency of biological products, including our nation's supply of blood products, are reviewed by the Center for Biologics Evaluation and Research (CBER). Additionally, CBER regulates diagnostic tests for retroviruses, including HIV, as well as devices used in cell and gene therapies. An Intercenter Agreement between CBER and CDRH identifies devices that CBER regulates.

MDUFMA Commitments: Goals and Approaches

The Medical Device User Fee and Modernization Act (MDUFMA) has three particularly significant provisions:

- **User fees for premarket reviews.** Premarket Applications (PMAs), Product Development Protocols (PDPs), Biologics Licensing Applications (BLAs), certain supplements, and 510(k)s (premarket notification submissions) are now subject to fees. The revenues from these fees, and from additional appropriations for infrastructure, will allow FDA to pursue a set of performance goals that will provide patients earlier access to safe and effective technology, and will provide more interactive and rapid review to the medical device industry. A small business (sales and receipts of $30 million or less) may pay a reduced fee. The payment of a premarket review fee is not related to FDA's final decision on a submission.
- **Establishment inspections may be conducted by accredited persons** (third-parties), under carefully prescribed conditions.

- **New regulatory requirements for reprocessed single-use devices**, including provisions requiring the submission of additional data on devices now being reprocessed, and a new category of premarket submission, the premarket report.

MDUFMA makes several other significant changes including:

- The existing third-party 510(k) review program is continued through FY 2006.
- The review of combination products (products that combine elements of devices, drugs, or biologics) will be coordinated by a new office (the Office of Combination Products) in the Office of the Commissioner.
- FDA may require electronic registration of device establishments, when feasible.
- Manufacturers may provide electronic labeling for prescription devices used in health care facilities.
- The sunset provision, which addresses how FDA is to determine the intended use of a device, is revoked.[3] The effect is to make the requirement permanent.
- The law now explicitly provides for modular review of PMAs.

[3] Applicable to section 513(i)(1)(E).

MDUFMA Implementation

In addition to authorizing the FDA to collect user fees for medical device applications, MDUFMA established review performance goals for the Agency. These goals aim to improve review times for medical device applications by up to 25 percent in five years (even more improvement is expected for breakthrough devices). FDA's medical device program resources have been reduced in recent years, and there have been indications that review performance had begun to decline. MDUFMA's review performance goals recognize that FDA will need a two-year start-up period (FY 2003 through FY 2004) to hire and train new staff and rebuild review program infrastructures before it will be possible to make substantial progress in improving overall review performance. Consequently, most review performance goals do not go into effect until FY 2005. User fees, coupled with additional appropriations from Congress, will help the FDA more efficiently and more quickly make safe and effective medical devices available to the public.

Current State: FY 2003 Activities and Accomplishments

In FY 2003, the Agency met all of its MDUFMA statutory deadlines and maintained current levels of medical device review performance. There was no opportunity for FDA to apply either of the two review performance goals for FY 2003 (both related to FDA action on an amendment containing a complete response to an "approvable" letter).[4] As a part of FDA's ongoing commitment to MDUFMA, the Agency is preparing, through guidance and procedural development, management initiatives, and outreach/education activities, to meet the more ambitious performance goals of FY 2005 – FY 2007.

- **Guidance and Procedural Development.** The Agency developed and published eleven guidance documents this year to help industry and FDA staff ensure that medical device applications are complete and reviewed as expeditiously as possible. These include guidances on the following:
    - Initial implementation of MDUFMA
    - Third party accreditation criteria
    - Reprocessed single-use devices
    - Pediatric expertise and protection of pediatric patients in clinical trials

[4] FDA could not apply these goals because the specified conditions for these two goals did not occur before FY 2003 ended. That is, there was no instance where 1) an applicant submitted an application on or after October 1, 2002 (the effective date of MDUFMA's review performance goals), 2) FDA issued an "approvable" letter for that application, 3) the applicant submitted an amendment containing a complete response to FDA's "approvable" letter, 4) 30 days passed for FDA to take action on the amendment, and 5) the 30-day period for FDA action closed before the end of FY 2003. FDA often makes a decision on a PMA without issuing an "approvable" letter.

The FDA also created, developed, and is currently administering billing and collection procedures for user fees under MDUFMA (FDA announced device user fees for FY 2004 on July 31, 2003). In addition, the Agency implemented provisions to reduce the financial burden on small business manufacturers. FDA granted 125 of 135 written requests for small business designations in FY 2003. All were completed within 2 days of receipt.

Appendix F contains a complete list and descriptions of these guidances published in FY 2003.

- **Public Notification.** FDA published several *Federal Register* notices during FY 2003 to implement MDUFMA requirements, to announce new guidance documents, and for other purposes. Examples include notices announcing MDUFMA user fee rates for FY 2003 and for FY 2004, a notice explaining fee payment procedures, and notices identifying the critical reprocessed single-use devices whose exemption from 510(k) is terminated and for which validation data is now required in a 510(k).

  Appendix G contains a complete list and descriptions of these *Federal Register* notices published in FY 2003.

- **Hiring and Management Initiatives.** The Agency designed and implemented several new systems to improve management of the medical device application review process. The Agency hired new staff, including 67 additional hires, bringing valuable expertise to the evaluation of medical devices. In addition, FDA Centers improved document distribution and handling systems (e.g., additional courier services, comprehensive bar coded tracking of deliveries, use of electronic submissions). The Agency also implemented electronic tracking systems (for example, MDUFMA payment tracking) and re-defined the roles and responsibilities for different levels of management and review. Additionally, CBER and CDRH renewed their commitment to the harmonization of their device review processes.

- **Outreach and Education Activities.** FDA initiated several activities to explain the many new requirements and provisions of MDUFMA to stakeholders. The Agency developed and launched an Internet site to provide information about MDUFMA to the medical device industry and the public (www.fda.gov/oc/mdufma) that includes essential reference materials such as legislation requirements, guidance documents, action dates, and information on meetings. FDA established an open docket (www.fda.gov/ohrms/dockets/dockets/02n0534/02n0534.htm) to encourage public input and interaction with program management and scheduled a public stakeholder meeting for December 3, 2003 (one year before the statutory requirement for an annual meeting). This meeting will focus on topics related to MDUFMA implementation: How the Process Is Working, Electronic Labeling, Bundling, Modular PMAs, Third Party Inspections, and Reprocessed Single-use Devices. In addition, the Agency sent letters to consumer organizations, trade organizations, and manufacturers about MDUFMA, gave briefings and presentations at numerous professional meetings, and responded to hundreds of thousands of phone calls and letters concerning MDUFMA's new requirements.

Implementation Plans for FY 2004

During FY 2004, FDA will expand its efforts, through employee hiring, training, guidance development, electronic tracking/review system expansion, and outreach, to improve the timeliness and efficiency of device review programs and build FDA's capacity to meet the more challenging goals set for later years.

- **Employee Hiring, Training, and Use of Outside Experts**. FDA will increase training on MDUFMA related guidance to help improve device review performance. FDA plans to hire approximately 50 new employees by the end of the fiscal year to help meet MDUFMA performance goals. The Agency also intends to increase the use of outside experts through the Medical Device Fellowship Program, which has already brought 12 outside experts, primarily clinicians and surgeons, to work with cardiovascular, orthopedic, neurology, and *in vitro* diagnostics (IVD) staff. More fellowships are planned for FY 2004.
- **Guidance**. FDA will provide required FY 2004 deliverables (guidances, reports, etc.) by the established deadlines. The Agency plans to issue guidance on bundling, modular PMAs, filing reviews, appeal procedures, and improvements to the timeliness of preapproval inspections.
- **Electronic Tracking Systems and Reviews**. FDA will expand its device database tracking systems with additional enhancements to provide for more efficient managerial oversight of review performance. In addition, FDA plans to invest in IT programs to speed reviews (electronic reviews).
- **Collaboration and Outreach Efforts**. FDA plans to continue CDRH-CBER joint workshops (e.g., IVD workshop, Best Practices Workshops). The Agency will also continue outreach efforts to stakeholders at such forums as Advisory Committee meetings, IVD Roundtables, and Stakeholder's Meeting.

Report on FY 2003 MDUFMA Performance

This report presents the Agency's performance on MDUFMA performance goals and commitments in FY 2003. Unless otherwise noted, all performance data in this section are as of September 30, 2003.

Performance Goals: For each type of submission for which a medical device user fee is assessed, MDUFMA requires that FDA meet specific performance goals. MDUFMA contains two types of performance goals:

- **Cycle Goals**. A cycle goal is a goal on a specified action that precedes a final action on the submission.

  For example, "First action major deficiency letters will issue within 120 days." A major deficiency letter is not a final action; the applicant can continue the review by preparing and submitting an amendment that addresses the deficiencies identified in FDA's letter.

- **Decision Goals**. A decision goal, on the other hand, is a goal on a final action, ending the review process.

  For example, "90% of submissions received in FY 2007 will have an FDA decision in 300 days."

Submissions received since the start of FY 2003 (October 1, 2002) are subject to MDUFMA's performance goals and will be reflected in FDA's performance statistics. Most of these goals do not begin until FY 2005 or FY 2006 to allow the agency time to collect user fees and put systems into place.

Performance Commitments: In addition to the performance goals, MDUFMA holds FDA to several commitments related to the medical device review process. These include, for example, programs and activities related to the application of user fee revenues, guidance development for the modular PMA review program[5], and examination of FDA's bundling policy[6].

Measuring Performance[7]. Progress on MDUFMA's performance goals and commitments is measured in different ways, based on the type of goal or commitment. The following types of measures were used to capture FDA's progress on meeting MDUFMA's performance goals and commitments in FY 2003:

- **Quantitative Measures**. MDUFMA's performance goals (cycle and decision goals)

[5] See Appendix A, section I, paragraph L.
[6] See Appendix A, section I, paragraph N.
[7] See Appendix H for a more detailed description of performance measures.

are quantifiable; that is, progress can be measured and described primarily through standard statistics (for example, number of submissions, mean review time, median review time, percent meeting a review time standard)

- **Descriptive Measures**. Alternatively, some MDUFMA commitments are more descriptive in nature. For these, progress is reported through narrative accounts outlining specific actions taken, in addition to any results attributed to those actions.

Receipt Cohort. All FDA review performance statistics are based on a receipt cohort. This methodology calculates performance statistics for submissions for the year they were received, regardless of when FDA ultimately acted on, approved, or cleared the submissions. A consequence of this approach is that the statistics shown for a particular year may change from one report to the next. This is because as time passes, FDA completes work on more and more submissions within a cohort. As more submissions are completed, the statistics for that year of receipt must be adjusted to reflect the new completions. Until all submissions in a cohort are completed, only a preliminary performance assessment can be provided for that cohort.

Original PMAs, Panel-Track Supplements, PMRs

Goal – Action on an amendment containing a complete response to an "approvable" letter within 30 days

The table below summarizes the one FY 2003 performance goal for Original Premarket Approvals (PMAs), Panel-Track PMA Supplements, and Premarket Reports (PMRs) under MDUFMA. [8] Actions on amendments containing a complete response to an "approvable" letter have a goal of 30 days. This goal and its associated performance level (90% on time) remain constant from FY 2003 to FY 2007.

Goal		On-Time Performance by Submission Year FY 03 – FY 07
Action on an amendment containing a complete response to an "approvable" letter	30 days	**90%**

Workload

The following table shows the number of original PMAs, Panel-Track PMA Supplements, and PMRs, received in FY 2003.

Submission Type	Number Received FY 03[9]
• **Original PMAs**	*55*[10]
• **Panel-Track PMA Supplements**	*7*
• **PMRs**	*0*
TOTAL	62

Performance

The conditions necessary to measure performance against this goal did not occur during FY 2003. FDA did not issue an "approvable" decision on any original PMAs, Panel-Track PMA Supplements, or PMR submissions, so there was no occasion for an applicant to submit an amendment in response. For additional information, see Appendix D.

[8] Section I, Paragraph A, Goal 4 of FDA's Commitment Letter

[9] The count of FY 2003 submissions assumes that all submissions received in the last two months of FY 2003 are filed. When FDA files a submission, it is deemed "complete" by MDUFMA definition. FDA makes a filing decision within 60 days of an original application's receipt. All calculations of MDUFMA review times are made, however, from the original receipt date of the filed application.

[10] Out of the 55 PMAs received during FY 2003 (the FY 2003 receipt cohort), FDA issued 11 PMA approval decisions during FY 2003 without first issuing an "approvable" letter; seven PMAs were *approved* and four were *approved subject to GMP inspection.*

Expedited Original PMAs

Goal – Action on an amendment containing a complete response to an "approvable" letter within 30 days

The table below summarizes the one FY 2003 performance goal for expedited original PMAs under MDUFMA.[11] Actions on amendments containing a complete response to an "approvable" letter have a goal of 30 days. This goal and its associated performance level (90% on time) remain constant from FY 2003 to FY 2007.

Goal		On-Time Performance by Submission Year FY 03 – FY 07
Action on an amendment containing a complete response to an "approvable" letter	30 days	**90%**

Workload

The following table shows the number of expedited original PMAs received in FY 2003.

Submission Type	Number Received FY 03[12]
• **Expedited Original PMAs**	*3*

Performance

The conditions necessary to measure performance against this goal did not occur during FY 2003. FDA did not issue an "approvable" decision on any expedited original PMAs so there was no occasion for an applicant to submit an amendment in response. For additional information, see Appendix D.

[11] Section I, Paragraph B, Goal 4 of FDA's Commitment Letter

[12] The count of FY 2003 submissions assumes that all submissions received in the last two months of FY 2003 are filed. When FDA files a submission, it is deemed "complete" by MDUFMA definition. FDA makes a filing decision within 60 days of an original application's receipt. All calculations of MDUFMA review times are made, however, from the original receipt date of the filed application.

Additional MDUFMA Performance Commitments

This section reports on the additional commitments outlined in FDA's Commitment Letter. A detailed description of the commitments, performance targets, and definitions of terms can be found in Appendix A (section I, paragraphs I - P).

Additional Efforts Related to Performance Goals. The Agency and the regulated industry agree that the use of both informal and formal meetings (e.g., determination and agreement meetings, informal pre-investigational device exemption (IDE) meetings, pre-PMA meetings, pre-PMA filing meetings) by both parties is critical to ensure high application quality such that the above performance goals can be achieved (section I, paragraph I).

> *FY 2003 Accomplishments*: FDA continues to encourage agency-sponsor meetings as a particularly effective way to ensure that both FDA and applicants understand the clinical, scientific, and technical issues both parties are seeking to resolve. During FY 2003, the Agency tracked four types of meetings: pre-IDE meetings, determination meetings, agreement meetings, and 100-day meetings. The pre-IDE meetings have proven to be the most useful to applicants; during FY 2003, FDA participated in 99 pre-IDE meetings. Applicants appear to be less interested in other types of meetings (during FY 2003, FDA participated in 4 agreement meetings, 1 determination meeting, and two 100-day meetings).

Maintenance of Current Performance. It is the intent of the Agency that in review areas where specific performance goals have not been identified, current performance will be maintained (section I, paragraph J).

> *FY 2003 Accomplishments:* Final results for FY 2003 are not yet available for all types of submissions (the FY 2003 receipt cohort remains open for many types of submissions), but FDA's preliminary examination of the available data indicates the timeliness of FDA medical device reviews not covered by a specific performance goal was comparable to, or better than, results for FY 2002. FDA will provide detailed information on performance of all types of reviews by the end of 2003:
>
> - CDRH will publish its Office of Device Evaluation Annual Report for FY 2003; this report will include data on reviews conducted by the Office of In Vitro Diagnostic Device Evaluation and Safety.
> - CBER will provide information on its medical device review performance on its Internet site.

Application of User Fee Revenues. The Agency intends to apply significant user fee revenues to support reviewer training and hiring and/or outside contracting to achieve the identified performance goals in a responsible and efficient manner (section I, paragraph K).

FY 2003 Accomplishments: FDA is working to strengthen and expand its capacity to conduct reviews to ensure the safety and effectiveness of new medical devices. The Agency is hiring the additional staff that will be needed to improve its device review processes and meet the performance goals established for the agency under MDUFMA. During FY 2003, FDA hired medical officers, consumer safety officers, chemists, microbiologists, biomedical engineers, statisticians, scientists, project managers, IT specialists, and other specialized staff. FDA has also expanded the Agency's use of IT contractors, providing additional flexibility to meet nonrecurring workloads, to augment FDA resources in highly specialized areas, and to perform particular tasks at a lower cost than would otherwise be possible.

Prior to enactment of an appropriation allowing FDA to begin collecting the medical device user fees authorized by MDUFMA, FDA did not have funds available to hire new staff. Additionally, FDA was prohibited from hiring new staff to implement MDUFMA until after FDA's appropriation for FY 2003 was passed by Congress and signed on February 20, 2003. Prior to that time, FDA began implementing MDUFMA with existing staff. FDA's implementation of MDUFMA accelerated during the second half of FY 2003, as the Agency was able to begin hiring and training new staff.

- For FY 2003, the Center for Devices and Radiological Health (CDRH) hired staff for 67 additional positions for MDUFMA implementation, and funded a total of approximately 681 FTEs for the process for the review of device applications.[13]
- The Center for Biologics Evaluation and Research (CBER) was allocated 11 additional FTEs for MDUFMA implementation, and funded approximately 59 FTEs for MDUFMA-related activities. Additional personnel were hired to impact review times, and funds were used to shorten and improve document delivery.

Both Centers have begun to train staff on the new guidance required to implement MDUFMA, and have developed plans to significantly increase clinical and technical training in the coming year.

Modular PMA Review Program. The Agency intends to issue guidance regarding the implementation of new section 515(c)(3) of the Federal Food, Drug, and Cosmetic Act. It is the intent of the Agency that once this program is implemented, the Agency will work with its stakeholders to develop appropriate performance goals for this program. Until such time, the Agency intends to review and close complete modules that are submitted well in advance of the PMA submission as expeditiously as possible (section I, paragraph L).

FY 2003 Accomplishments: FDA issued initial guidance on modular PMA reviews in the guidance document, *Assessing User Fees: PMA Supplement Definitions, Modular PMA*

[13] The "process for the review of device applications" is defined by section 737(5) of the FD&C Act. See Appendix B for the full text of the definition.

Fees, BLA and Efficacy Supplement Definitions, Bundling Multiple Devices in a Single Application, and Fees for Combination Products (www.fda.gov/cdrh/mdufma/guidance/1201.html), on February 25, 2003. This guidance announces that the fee for a modular PMA submission is due upon submission of the first module (not just the "shell" that describes the overall plan for the modular submission). If an applicant submitted the first module (again, not just the shell) prior to the October 1, 2002 effective date of MDUFMA, FDA has determined that no fee will be required.[14] FDA will provide more comprehensive guidance early in FY 2004, and will consult with stakeholders to develop performance goals for modular PMAs.

"Follow-On" Licensed Devices. The Center for Biologics Evaluation and Research will, if feasible, identify a category of "follow-on" licensed devices and collect information to determine whether alternative performance goals for such a category are appropriate (section I, paragraph M).

FY 2003 Accomplishments: CBER has been following a phased approach to the implementation of MDUFMA, focusing initially on timeliness and quality of review performance. During FY 2003, CBER continued to make case-by-case decisions, based on FDA's least-burdensome guidance. During FY 2004, CBER will initiate discussions intended to identify follow-on devices and the feasibility of adjusted time frames for their review. Stakeholder input will be sought on possible approaches.

Bundling Policy. The Agency will, in consultation with its stakeholders, consider the issue of bundling for products with multiple related submissions. After such consultation, the Agency will either issue guidance on bundling or publish a notice explaining why it has determined that bundling is inappropriate (section I, paragraph N).

FY 2003 Accomplishments: After consulting with stakeholders, FDA determined that bundling is appropriate in the right circumstances. FDA issued initial guidance on bundling of multiple related submissions in the guidance document, *Assessing User Fees: PMA Supplement Definitions, Modular PMA Fees, BLA and Efficacy Supplement Definitions, Bundling Multiple Devices in a Single Application, and Fees for Combination Products* (www.fda.gov/cdrh/mdufma/guidance/1201.html), issued on February 25, 2003. This guidance explains that bundling may involve multiple devices or multiple indications for use. After issuing this preliminary guidance, the Agency continued to consult with stakeholders, and as a result will provide more comprehensive guidance on bundling early in FY 2004.

Electronic Review of Applications. The Agency will continue its efforts toward development of electronic receipt and review of applications, as expeditiously as possible, acknowledging that insufficient funding is included in the user fee program for this effort (section I, paragraph O).

[14] During FY 2003, 24 modular PMAs were not subject to a fee under this policy. FDA has an additional 28 modular PMAs open which will not be subject to a fee.

FY 2003 Accomplishments: FDA is continuing to work toward future implementation of electronic systems for the receipt and review of product applications and other submissions. FDA will expand its use of electronic submissions as resources permit.

- CBER has published Guidance for Industry, *Providing Regulatory Submissions to CBER in Electronic Format - Investigational New Drug Applications (INDs)* (www.fda.gov/cber/gdlns/eind.htm) (March 26, 2002), which applies to investigational studies of devices, such as blood screening test kits, leading to a BLA. CBER has contributed to guidance documents on electronic submissions in general, and CBER has received a number of electronic submissions for biologic (non-device) reviews. Through FY 2003, CBER had not received electronic document submissions of IDEs, PMAs, or 510(k)s.

  CBER continues to make significant outreach efforts to inform regulated industry of the process for electronic submissions to CBER. In particular, during all sponsor meetings, CBER informs applicants and potential applicants of the ability to submit electronic documents.

- CDRH worked with applicants to expand the use of electronic submissions during FY 2003. During FY 2003, 29 sponsors sent 97 submissions entirely in electronic form (compared with 14 sponsors and 73 submissions during FY 2002).

Preapproval Inspections. The Agency will plan to improve the scheduling and timeliness of preapproval inspections. The Agency will monitor the progress of these efforts and provide such information in the annual performance report (section I, paragraph P).

FY 2003 Accomplishments: During FY 2003, FDA began an examination of the factors affecting the timeliness of preapproval inspections to determine how the process can best be improved and what resources would be required to make those improvements. During FY 2004, FDA expects to commit to specific performance goals for preapproval inspections, issue guidance for FDA staff and industry, and will begin making the process improvements necessary to achieve those goals.

Appendix A

November 14, 2002 Commitment Letter from DHHS Secretary Thompson to Congress

THE SECRETARY OF HEALTH AND HUMAN SERVICES,

Washington, DC, November 14, 2002.

Hon. EDWARD KENNEDY,
U.S. Senate,
Washington, DC.

DEAR MR. CHAIRMAN. As you are aware, the Medical Device User Fee and Modernization Act of 2002 was signed by the President on October 26, 2002. Under Title I, the additional revenues generated from fees paid by the medical device industry will be used to expedite the medical device review process, in accordance with performance goals that were developed by the Food and Drug Administration (FDA) in consultation with the industry.

FDA has worked with various stakeholders, including representatives from consumer, patient, and health provider groups, and the medical device industry to develop legislation and goals that would enhance the success of the device review program. Title I of the Medical Device User Fee and Modernization Act of 2002 reflects the fee mechanisms and other improvements developed in these discussions. The performance goals referenced in Section 101 are specified in the enclosure to this letter, entitled "Performance Goals and Procedures." I believe they represent a realistic projection of what FDA can accomplish with industry cooperation and the additional resources identified in the bill.

This letter and the enclosed goals document pertain only to title I (Fees Related to Medical Devices) of Public Law 107-250, Medical Device User Fee and Modernization Act of 2002. OMB has advised that there is no objection to the presentation of these views from the standpoint of the Administration's program. We appreciate the support of you and your staffs, the assistance of other Members of the Committee, and that of the Appropriations Committees, in the authorization of this vital program.

Sincerely,

TOMMY G. THOMPSON.

MDUFMA PERFORMANCE GOALS AND PROCEDURES

The performance goals and procedures of the FDA Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER), as agreed to under the medical device user fee program in the Medical Device User Fee and Modernization Act of 2002, are summarized as follows:

I. REVIEW PERFORMANCE GOALS — FISCAL YEAR 2003 THROUGH 2007

All references to "days" mean "FDA days."

A. ORIGINAL PREMARKET APPROVAL (PMA), PANEL-TRACK PMA SUPPLEMENT, AND PREMARKET REPORT SUBMISSIONS

1. The following cycle goals apply to: 75% of submission received in fiscal year 2005; 80% of submissions received in fiscal year 2006; 90% of submissions received in fiscal year 2007.

(a) First action major deficiency letters will issue within 150 days.

(b) All other first action letters (approval, approvable, approvable pending good manufacturing practices (GMP) inspection, not approvable, or denial) will issue within 180 days.

(c) Second or later action major deficiency letters will issue within 120 days.

(d) Amendments containing a complete response to major deficiency or not approvable letters will be acted on within 180 days.

2. Decision Goals:

(a) 80% of submissions received in fiscal year 2006 will have an FDA decision in 320 days.

(b) 90% of submissions received in fiscal year 2007 will have an FDA decision in 320 days.

3. Subject to the following paragraph, 50% of submissions received in fiscal year 2007 will have an FDA decision in 180 days.

This goal will be re-evaluated following the end of fiscal year 2005. FDA will hold a public meeting to consult with its stakeholders and to determine whether this goal is appropriate for implementation in fiscal year 2007. If FDA determines that the goal is not appropriate, prior to August 1, 2006, the Secretary will send a letter to the Committee on Health, Education, Labor and pensions of the Senate and to the Energy and Commerce Committee, Subcommittee on Health of the House of Representatives stating that the goal will not be implemented and the rationale for its removal.

4. 90% of amendments containing a complete response to an approvable letter received in fiscal years 2003 through 2007 will be acted on within 30 days.

B. EXPEDITED ORIGINAL PMA SUBMISSIONS

1. The following goals apply to PMA submissions where:

(a) FDA has granted the application expedited status;

(b) The applicant has requested and attended a pre-filing review meeting with FDA;

(c) The applicant's manufacturing facilities are prepared for inspection upon submission of the application; and

(d) The application is substantively complete, as defined at the pre-filing review meeting.

2. The following cycle goals apply to: 70% of submissions received in fiscal year 2005; 80% of submissions received in fiscal year 2006; 90% of submissions received in fiscal year 2007.

(a) First action major deficiency letters will issue within 120 days.

(b) All other first action letters (approval, approvable, approvable pending GMP inspection, not approvable, or denial) will issue within 170 days.

(c) Second or later action major deficiency letters will issue within 100 days.

(d) Amendments containing a complete response to major deficiency or not approvable letters will be acted on within 170 days.

3. Decision Goals:

(a) 70% of submissions received in fiscal year 2005 will have an FDA decision in 300 days.

(b) 80% of submissions received in fiscal year 2006 will have an FDA decision in 300 days.

(c) 90% of submissions received in fiscal year 2007 will have an FDA decision in 300 days.

4. 90% of amendments containing a complete response to an approvable letter received in fiscal years 2003 through 2007 will be acted on within 30 days.

C. 180-DAY PMA SUPPLEMENT SUBMISSIONS

1. The following goals apply to: 80% of submissions in fiscal year 2005; 85% of submissions in fiscal year 2006; 90% of submissions in fiscal year 2007.

(a) First action not approvable letters will issue within 120 days.

(b) All other first action letters (approval, approvable, approvable pending GMP inspection, or denial) will issue within 180 days.[15]

(c) Amendments containing a complete response to a not approvable letter will be acted on within 160 days.

2. Decision Goals:

(a) 80% of submissions received in fiscal year 2005 will have an FDA decision in 180 days.

(b) 80% of submissions received in fiscal year 2006 will have an FDA decision in 180 days.

(c) 90% of submissions received in fiscal year 2007 will have an FDA decision in 180 days.

3. Current performance for real-time review PMA supplement submissions will be maintained.

[15] This text was edited from the original version. "Not approvable" was taken out of the list of "All other first action letters." Because "Not approvable" letter is already captured under the "First Action" goal of 120 days, it should not be repeated under the "All other first actions" goal of 180 days.

D. 510(k) SUBMISSIONS

1. The following goals apply to: 70% of submissions received in fiscal year 2005; 80% of submissions received in fiscal year 2006; 90% of submissions received in fiscal year 2007.

(a) First action additional information letters will issue within 75 days.

(b) Subsequent action letters will issue within 60 days.

2. Decision Goals:

(a) 75% of submissions received in fiscal years 2005 and 2006 will have an FDA decision in 90 days.

3. Subject to the following paragraph, 80% of submissions received in fiscal year 2007 will have an FDA decision in 90 days.

This goal will be re-evaluated following the end of fiscal year 2005. FDA will hold a public meeting to consult with its stakeholders and to determine whether this goal is appropriate for implementation in fiscal year 2007. If FDA determines that the goal is not appropriate, prior to August 1, 2006, the Secretary will send a letter to the Committee on Health, Education, Labor and Pensions of the Senate and to the Energy and Commerce Committee, Subcommittee on Health of the House of Representatives stating that the goal will not be implemented and the rationale for its removal, and that the goal for fiscal year 2006 will be implemented for fiscal year 2007.

E. ORIGINAL BIOLOGICS LICENSING APPLICATIONS (BLAs)

The following goals apply to: 75% of submissions received in fiscal year 2006; 90% of submissions received in fiscal year 2007.

1. Review and act on standard original BLA submissions within 10 months of receipt.

2. Review and act on priority original BLA submissions within 6 months of receipt.

F. BLA EFFICACY SUPPLEMENTS

The following goals apply to: 75% of submissions received in fiscal year 2006; 90% of submissions received in fiscal year 2007.

1. Review and act on standard BLA efficacy supplement submissions within 10 months of receipt.

2. Review and act on priority BLA efficacy supplement submissions within 6 months of receipt.

G. ORIGINAL BLA AND BLA EFFICACY SUPPLEMENT RESUBMISSIONS

The following goals apply to: 75% of submissions received in fiscal year 2005; 80% of submissions received in fiscal year 2006; 90% of submissions received in fiscal year 2007.

1. Review and act on Class 1 original BLA and BLA efficacy supplement resubmissions within 2 months of receipt.

2. Review and act on Class 2 original BLA and BLA efficacy supplement resubmissions within 6 months of receipt.

H. BLA MANUFACTURING SUPPLEMENTS REQUIRING PRIOR APPROVAL

The following goal applies to: 75% of submissions received in fiscal year 2006; 90% of submissions received in fiscal year 2007.

Review and act on BLA manufacturing supplements requiring prior approval within 4 months of receipt.

I. ADDITIONAL EFFORTS RELATED TO PERFORMANCE GOALS

The Agency and the regulated industry agree that the use of both informal and formal meetings (e.g., determination and agreement meetings, informal pre-investigational device exemption (IDE) meetings, pre-PMA meetings, pre-PMA filing meetings) by both parties is critical to ensure high application quality such that the above performance goals can be achieved.

J. MAINTENANCE OF CURRENT PERFORMANCE

It is the intent of the Agency that in review areas where specific performance goals have not been identified, current performance will be maintained.

K. APPLICATION OF USER FEE REVENUES

The Agency intends to apply significant user fee revenues to support reviewer training and hiring and/or outside contracting to achieve the identified performance goals in a responsible and efficient manner.

L. MODULAR PMA REVIEW PROGRAM

The Agency intends to issue guidance regarding the implementation of new section 515(c)(3) of the Federal Food, Drug, and Cosmetic Act. It is the intent of the Agency that once this program is implemented, the Agency will work with its stakeholders to develop appropriate performance goals for this program. Until such time, the Agency intends to review and close complete modules that are submitted well in advance of the PMA submission as expeditiously as possible.

M. "FOLLOW-ON" LICENSED DEVICES

The Center for Biologics Evaluation and Research will, if feasible, identify a category of "follow-on" licensed devices and collect information to determine whether alternative performance goals for such a category are appropriate.

N. BUNDLING POLICY

The Agency will, in consultation with its stakeholders, consider the issue of bundling for products with multiple related submissions. After such consultation, the Agency will either issue guidance on bundling or publish a notice explaining why it has determined that bundling is inappropriate.

O. ELECTRONIC REVIEW OF APPLICATIONS

The Agency will continue its efforts toward development of electronic receipt and review of applications, as expeditiously as possible, acknowledging that insufficient funding is included in the user fee program for this effort.

P. PREAPPROVAL INSPECTIONS

The Agency will plan to improve the scheduling and timeliness of preapproval inspections. The Agency will monitor the progress of these efforts and provide such information in the annual performance report.

II. ANNUAL STAKEHOLDER MEETING

Beginning in fiscal year 2004, FDA will hold annual public meetings to review and evaluate the implementation of this program in consultation with its stakeholders.

III. DEFINITIONS AND EXPLANATION OF TERMS

A. For original PMA submissions, Panel-Track PMA supplement submissions, expedited original PMA submissions, 180-day supplement submissions, and premarket report submissions, issuance of one of the following letters is considered to be an FDA decision:

1. approval
2. approvable
3. approvable pending GMP inspection
4. not approvable
5. denial

B. For 510(k) submissions, issuance of one of the following letters is considered to be an FDA decision:

1. substantially equivalent (SE)
2. not substantially equivalent (NSE)

C. Submission of an unsolicited major amendment to an original PMA submission, Panel-Track PMA supplement submission, expedited original PMA submission, 180-day supplement submission, or premarket report submission extends the FDA decision goal date by the number of days equal to 75% of the difference between the filing date and the date of receipt of the amendment. The submission of the unsolicited major amendment is also considered an action that satisfies the first or later action goal, as applicable.

D. For BLA (original, efficacy supplement, or manufacturing supplement) submissions, the term "review and act on" is understood to mean the issuance of a complete action letter after the complete review of a filed complete application. The action letter, if it is not an approval, will set forth in detail the specific deficiencies and, where appropriate, the actions necessary to place the application in condition for approval.

E. For original BLA and BLA efficacy supplement resubmissions:

1. Class 1 resubmitted applications are applications resubmitted after a complete response letter that include the following items only (or combinations of these items):

(a) Final printed labeling
(b) Draft labeling
(c) Safety updates submitted in the same format, including tabulations, as the original safety submission with new data and changes highlighted (except when large amounts of new information including important new adverse experiences not previously reported with the product are presented in the resubmission)
(d) Stability updates to support provisional or final dating periods
(e) Commitments to perform Phase 4 studies, including proposals for such studies
(f) Assay validation data
(g) Final release testing on the last 1-2 lots used to support approval
(h) A minor reanalysis of data previously submitted to the application (determined by the agency as fitting the Class 1 category)
(i) Other minor clarifying information (determined by the Agency as fitting the Class 1 category)
(j) Other specific items may be added later as the Agency gains experience with the scheme and will be communicated via guidance documents to industry.

2. Class 2 resubmissions are resubmissions that include any other items, including any item that would require presentation to an advisory committee.

Appendix B

Definition of the "Process for the Review of Device Applications" Section 737(5) of the FD&C Act

(5) The term 'process for the review of device applications' means the following activities of the Secretary with respect to the review of premarket applications, premarket reports, supplements, and premarket notification submissions:

(A) The activities necessary for the review of premarket applications, premarket reports, supplements, and premarket notification submissions.

(B) The issuance of action letters that allow the marketing of devices or which set forth in detail the specific deficiencies in such applications, reports, supplements, or submissions and, where appropriate, the actions necessary to place them in condition for approval.

(C) The inspection of manufacturing establishments and other facilities undertaken as part of the Secretary's review of pending premarket applications, premarket reports, and supplements.

(D) Monitoring of research conducted in connection with the review of such applications, reports, supplements, and submissions.

(E) Review of device applications subject to section 351 of the Public Health Service Act for an investigational new drug application under section 505(i) or for an investigational device exemption under section 520(g) and activities conducted in anticipation of the submission of such applications under section 505(i) or 520(g).

(F) The development of guidance, policy documents, or regulations to improve the process for the review of premarket applications, premarket reports, supplements, and premarket notification submissions.

(G) The development of voluntary test methods, consensus standards, or mandatory performance standards under section 514 in connection with the review of such applications, reports, supplements, or submissions and related activities.

(H) The provision of technical assistance to device manufacturers in connection with the submission of such applications, reports, supplements, or submissions.

(I) Any activity undertaken under section 513 or 515(i) in connection with the initial classification or reclassification of a device or under section 515(b) in connection with any requirement for approval of a device.

(J) Evaluation of postmarket studies required as a condition of an approval of a premarket application under section 515 or section 351 of the Public Health Service Act.

(K) Compiling, developing, and reviewing information on relevant devices to identify safety and effectiveness issues for devices subject to premarket applications, premarket reports, supplements, or premarket notification submissions.

Appendix C: Summary of MDUFMA's Quantitative Goals

This table summarizes all of MDUFMA's quantifiable review performance goals (section I, goals A through H, in Secretary Thompson's November 14, 2002 commitment letter).

Activity	Review Time	Baseline FY 1999 - FY 2001	Performance Level (by FY) (— indicates no goal)				
			2003	2004	2005	2006	2007
PMAs, Panel-Track Supplements[16]							
• FDA decision (approval, approvable, approvable pending GMP inspection, not approvable, denial)	320 days	78% - 80%	—	—	—	80%	90%
	180 days	42% - 43 %	—	—	—	—	50%
• First action – "major deficiency" letter	150 days	67%	—	—	75%	80%	90%
• First action – all other first actions (approval, approvable, approvable pending GMP inspection, not approvable, or denial)	180 days	86%	—	—	75%	80%	90%
• Second or later action – "major deficiency" letter	120 days	52%	—	—	75%	80%	90%
• Action on an amendment containing a complete response to a "major deficiency" or "not approvable" letter	180 days	89%	—	—	75%	80%	90%
• Action on an amendment containing a complete response to an "approvable" letter	30 days	74%	90%	90%	90%	90%	90%
Expedited PMAs							
• FDA decision (approval, approvable, approvable pending GMP inspection, not approvable, denial)	300 days	70%	—	—	70%	80%	90%
• First action – "major deficiency" letter	120 days	46%	—	—	70%	80%	90%
• First action – all other first actions (approval, approvable, approvable pending GMP inspection, not approvable, or denial)	170 days	70%	—	—	70%	80%	90%
• Second or later action – "major deficiency" letter	100 days	50%	—	—	70%	80%	90%
• Action on an amendment containing a complete response to a "major deficiency" or "not approvable" letter	170 days	79%	—	—	70%	80%	90%
• Action on an amendment containing a complete response to an "approvable" letter	30 days	83%	90%	90%	90%	90%	90%

[16] There are five PMAs/Panel-Track Supplements from FY 1999-FY2001 that do not have an FDA decision. All five are awaiting a response from the applicant. When FDA receives a response, we will resume our review, and the additional time may affect certain baseline performance measures. For the "FDA decision", we have provided a best- and worst- case range showing the maximum variation that may occur in the performance measure. The "FDA decision – median performance" will not change, as there are several decisions with the same measure clustered together. Thus, regardless of the final decisions on the five open applications, the median performance measure will stay the same. In addition, the two "first action" measures will not change, as there has been a first action on all of the open applications. Some change is possible for the remaining performance measures, but it is not possible to estimate the range, because there can be multiple actions for each applicant.

Activity	Review Time	Baseline FY 1999 - FY 2001	Performance Level (by FY) (— indicates no goal)				
			2003	2004	2005	2006	2007
180-day Supplements							
• FDA decision (approval, approvable, approvable pending GMP inspection, not approvable, denial)	180 days	89%	—	—	80%	85%	90%
• First action – "not approvable" letter	120 days	17%	—	—	80%	85%	90%
• First action – all other first actions (approval, approvable, approvable pending GMP inspection, or denial)[17]	180 days	89%	—	—	80%	85%	90%
• Action on an amendment containing a complete response to a "not approvable" letter	160 days	68%	—	—	80%	85%	90%
510(k)s							
• FDA decision (SE, NSE, and other final decisions)	90 days	77%	—	—	75%	75%	80%
• First action – "additional information" letter	75 days	57%	—	—	70%	80%	90%
• Second or later action	60 days	42%	—	—	70%	80%	90%
Biologics Licensing Applications (BLAs)							
• Review and act on standard original BLAs (issue "complete action" letter)	10.0 months	8%	—	—	75%	80%	90%
• Review and act on priority original BLA submissions (issue "complete action" letter)	6.0 months	100%	—	—	75%	80%	90%
BLA Supplements							
• Review and act on standard BLA efficacy supplements (issue "complete action" letter)	10.0 months	No Data Available.	—	—	—	75%	90%
• Review and act on priority BLA efficacy supplements (issue "complete action" letter)	6.0 months	No Data Available.	—	—	—	75%	90%
• Review and act on BLA manufacturing supplements that require prior approval (issue "complete action" letter)	4.0 months	48%	—	—	—	75%	90%
BLA Resubmissions, BLA Supplement Resubmissions							
• Review and act on a Class 1 resubmission to an original BLA or BLA efficacy supplement (issue "complete action" letter)	2.0 months	No Data Available.	—	—	75%	80%	90%
• Review and act on a Class 2 resubmission to an original BLA or BLA efficacy supplement (issue "complete action" letter)	6.0 months	100%	—	—	75%	80%	90%

[17] This is a slightly edited revision of the goal as defined in FDA's commitment letter. "Not approvable" was taken out of the list of "All other first actions." Because "Not approvable" letter is already captured under the "First Action" goal of 120 days, it should not be repeated under the "All other first actions" goal of 180 days.

Appendix D: FY 2003 Quantitative Goal Performance

The following tables provide a detailed summary of FDA's performance related to the MDUFMA quantitative goals for FY 2003.

Table 1

Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions

Performance Goal: 90% of amendments containing a complete response to an approvable letter will be acted on within 30 days

Note: The conditions necessary to measure performance against this goal did not occur during FY 2003.

	FY 2003 Performance				
Type of application	Receipts	FDA "approvable" decisions	Amendments received containing a complete response to an "approvable" letter	FDA action within 30 days of receipt	Percent within 30 days of receipt
Original PMA	55[18]	None	—	—	—
Panel-track PMA supplement	7	None	—	—	—
Premarket report (PMR)	None	—	—	—	—
Total	62	None	—	—	—

Table 2

Expedited Original PMA Submissions

Performance Goal: 90% of amendments containing a complete response to an approvable letter will be acted on within 30 days

Note: The conditions necessary to measure performance against this goal did not occur during FY 2003.

	FY 2003 Performance				
Type of application	Receipts	FDA "approvable" decisions	Amendments received containing a complete response to an "approvable" letter	FDA action within 30 days of receipt	Percent within 30 days of receipt
Expedited Original PMA	3	None	—	—	—

[18] Out of the 55 PMAs received during FY 2003 (the FY 2003 receipt cohort), FDA issued 11 PMA approval decisions during FY 2003 without first issuing an "approvable" letter: Seven PMAs were *approved* and four were *approved subject to GMP inspection.*

Appendix E: Summary of FY 2003 Performance

The following table provides a summary of the FY 03 MDUFMA Goals, as outlined by FDA's Commitment Letter, and FDA's progress towards meeting these goals. FDA's FY 2003 performance was consistent with MDUFMA goals and expectations.

Goals in Effect for FY 2003	FDA Performance	Met or Exceeded FY 03 Goal
Original premarket approval (PMA), panel-track PMA supplement, and premarket report submissions: 90% of amendments containing a complete response to an approvable letter will be acted on within 30 days.	No "approvable" letters issued during FY 2003.	---
Original expedited PMA submissions: 90% of amendments containing a complete response to an approvable letter will be acted on within 30 days.	No "approvable" letters issued during FY 2003.	---
Additional efforts related to performance goals	FDA held 99 pre-IDE meetings during FY 2003, more than any prior year.	
Maintenance of current performance.	FY 2003 performance was comparable to, or better than, FY 2002.	
Application of user fee revenues.	FDA began hiring and training new staff, began to rebuild review infrastructures.	
Modular PMA review program.	FDA issued interim guidance.	
"Follow-on" licensed devices.	Deferred until FY 2004.	
Bundling policy.	FDA issued interim guidance.	
Electronic review of applications.	FDA issued guidance on electronic submission of INDs that lead to BLAs for devices.	
Preapproval inspections.	FDA began an examination of the factors that affect timeliness of preapproval inspections.	

= Performance/progress meets or exceeds goal.
--- = Not measurable.
X = Goal not met.

Appendix F: Summary of FY 2003 Guidance Documents

In FY 2003, the FDA developed and published eleven guidance documents related to MDUFMA implementation. The following provides a summary of these guidances:

DOCUMENT TITLE/ DATE ISSUED	CONTENT
Assessing User Fees: PMA Supplement Definitions, Modular PMA Fees, BLA and Efficacy Supplement Definitions, Bundling Multiple Devices in a Single Application, and Fees for Combination Products; Guidance for Industry and FDA *(www.fda.gov/cdrh/mdufma/guidance/1201.html)* February 25, 2003	• Explains FDA's initial implementation of procedures required to determine whether an application is subject to a user fee, and the type of any fee to be assessed. • Describes how to distinguish among the various types of PMA supplements. • Explains that the fee for a modular PMA is due upon submission of the first module and that no fee will be assessed for a modular PMA if the first module (not just the shell) was submitted prior to October 1, 2002. • Provides information on BLAs and the types of BLA supplements that are, and are not, subject to fees. • Clarifies guiding principles on when bundling of multiple devices, or multiple indications, is appropriate. • Provides information on how fees will be assessed for combination products.

DOCUMENT TITLE/ DATE ISSUED	CONTENT
Section 206 of the Medical Device User Fee and Modernization Act (MDUFMA) (New Section 502(f) of the Federal Food, Drug, and Cosmetic Act) Electronic Labeling for Prescription Devices Intended for Use in Health Care Facilities (*www.fda.gov/cdrh/mdufma/bluebook/g03-1.html*) March 31, 2003	• Explains the general principles FDA will apply to implement section 502(f) of the FD&C Act concerning electronic labeling for prescription devices intended for use in health care facilities.
Implementation of the Inspection by Accredited Persons Program under MDUFMA; Accreditation Criteria *(www.fda.gov/cdrh/mdufma/guidance/1200.html)* April 28, 2003	• Explains how FDA will implement section 704(g) of the FD&C Act by accrediting third-parities to conduct Quality Systems/GMP inspections of eligible manufactures of class II and class III medical devices. • Outlines how third-party inspections will be conducted. • Provides information on the requirements a third-party must meet to be accredited by FDA to conduct inspections.[19]
Validation Data in Premarket Notification Submissions [510(k)s] for Reprocessed Single-Use Medical Devices *(www.fda.gov/cdrh/ode/guidance/1216.html)* July 8, 2003	• Discusses the types of validation data FDA recommends be submitted regarding cleaning, sterilization, and funcation performance to show a critical reprocessed single-use device[20] remains substantially equivalent after reprocessing.

[19] An FDA-accredited third-party may inspect a manufacturer of class II and class III devices if strict eligibility requirements are met by the establishment and the selected third-party. A third-party must meet specific accreditation criteria; not be affiliated, nor provide consultant services to medical device establishments; and the third party is subject to periodic audits to ensure they "continue to meet the standards of accreditation."

[20] By April 26, 2004, FDA will also identify the types of semi-critical reprocessed single-use devices for which validation data is required. Validation data for those reprocessed devices that already have a 510(k) will be required by January 26, 2004. However, FDA has also published a list of previously exempt reprocessed single use devices and will reconsider existing exemptions from 510(k) for certain reprocessed critical and semi-critical devices.

DOCUMENT TITLE/ DATE ISSUED	CONTENT
Pediatric Expertise for Advisory Panels *(www.fda.gov/cdrh/ode/guidance/1208.html)* June 3, 2003	• Defines pediatric population subgroups. • Discusses the circumstances where FDA expects to employ pediatric expertise on an FDA advisory committee that will provide advice concerning a device. • Outlines FDA staff responsibilities in ensuring that pediatric expertise is available when the device is intended for pediatric use.[21]
MDUFMA Small Business Qualification Worksheet and Certification *(www.fda.gov/cdrh/mdufma/guidance/1204.html)* March 27, 2003	• Explains how to qualify for small business fees for applications received by FDA during FY 2003 (October 1, 2002 through September 30, 2003). • Provides the FY 2003 MDUFMA Small Business Qualification Certification, Form FDA 3602.
Premarket Approval Application Filing Review *(www.fda.gov/cdrh/ode/guidance/297.html)* May 1, 2003	• Expands and clarifies FDA procedures for filing PMA applications.
Determination of Intended Use for 510(k) Devices (*www.fda.gov/cdrh/ode/guidance/857.html*) December 2, 2002	• Reflects MDUFMA's elimination of the sunset provision of section 513(i)(1)(E) of the FD&C Act. • Provides procedures for determining the intended use of a device that is subject to premarket notification.
Identification of Manufacturer of Medical Devices (Draft Guidance) *(www.fda.gov/cdrh/comp/guidance/1217.html)* June 23, 2003	• Responds to section 502(u) of the FD&C Act, added by section 301 of MDUFMA, requiring a device to prominently and conspicuously bear the name of the manufacturer, or an abbreviation or symbol that is generally recognized as identifying the manufacturer. • Advises the public that FDA does not intend to object if a manufacturer has not fully implemented the changes required by section 502(u) for up to 18 months after FDA issues a final guidance explaining the interpretation and implementation of this provision.

[21] Although MDUFMA amended the premarket approval section of the statute, CDRH will include pediatric expertise on an advisory panel, when appropriate, for all types of premarket submissions (i.e., PMA, product development protocol (PDP), 510(k), humanitarian device exemption (HDE), de novo applications, and investigational device exemption (IDE)). FDA will also include pediatric expertise on advisory panels when there are labeled indications for pediatric use or there is a reasonable likelihood of pediatric use.

DOCUMENT TITLE/ DATE ISSUED	CONTENT
Premarket Assessment of Pediatric Medical Devices (Draft Guidance) *(www.fda.gov/cdrh/ mdufma/guidance/1220. html)* July 24, 2003	• Defines pediatric population subgroups. • Discusses the types of information necessary to assure the safety and effectiveness of pediatric devices. • Outlines recommended protections for children in clinical trials of pediatric devices.
FY 2004 MDUFMA Small Business Qualification Worksheet and Certification *(www.fda.gov/cdrh/ mdufma/guidance/1225. html)* August 1, 2003	• Explains how to qualify for small business fees for applications received by FDA during FY 2004 (October 1, 2003 through September 30, 2004). The criteria are the same as for FY 2003. • Provides the FY 2004 MDUFMA Small Business Qualification Certification, Form FDA 3602 (For FY 2004).

Appendix G: Summary of Federal Register Notices

The following table summarizes all Federal Register notices relating to MDUFMA published through September 30, 2003:

DATE	SUBJECT	CITATION	COMMENT / ACTION DATE
11/21/2002	Establishment of Medical Device User Fee Rates for Fiscal Year 2003 and Interim Procedures.	67 F.R. 70228	—
	• 1/10/2003 — Correction — A 510(k) submitted during FY 2003 is not eligible for a reduced small business fee. Fee for any 510(k) submitted during FY 2003 is $2,187.	68 F.R. 1469	—
	• 1/22/2003 — Correction — Same intent.	68 F.R. 3033	—
2/4/2003	Establishment of a Public Docket.	68 F.R. 5643	Any time.
2/20/2003	Request for comments on proposed information collection — MedWatch: The FDA Medical Products Reporting Program. (60-day notice.) Section 202 of MDUFMA directs FDA to modify MedWatch forms to facilitate the reporting of information pertaining to reprocessed single-use devices. Also see 4/29/2003 (request for comments) and 10/10/2003 (OMB approval).	68 F.R. 6752	4/11/2003
2/25/2003	Medical Device User Fee Payment Procedures.	68 F.R. 8773	—
2/26/2003	Request for comments on proposed information collection — Medical Device User Fee Cover Sheet; Form FDA 3601. (60-day notice.) Also see 5/21/2003 (request for comments) and 8/25/2003 (OMB approval).	68 F.R. 8907	4/28/2003
3/26/2003	Agency Emergency Processing Under OMB Review; Fiscal Year 2003 MDUFMA Small Business Qualification Certification (Form FDA 3602). Also see 4/28/2003 (OMB approval).	68 F.R. 14664	4/25/2003
3/27/2003	Availability of Guidance — Fiscal Year 2003 MDUFMA Small Business Qualification Worksheet and Certification.	68 F.R. 14992	Any time.
4/28/2003	Announcement of OMB Approval of Information Collection; Fiscal Year 2003 MDUFMA Small Business Qualification Certification (Form FDA 3602). This approval expires 10/31/2003 (form will not be used after 9/30/2003; see 7/18/2003 for notice on replacement form). Also see 3/26/2003 (emergency submission to OMB).	68 F.R. 22387	—

DATE	SUBJECT	CITATION	COMMENT / ACTION DATE
4/28/2003	Agency Emergency Processing Under OMB Review; Inspection by Accredited Persons Under MDUFMA. Also see 6/26/2003 (OMB approval).	68 F.R. 22388	5/28/2003
4/28/2003	Availability of Guidance — Implementation of the Inspection by Accredited Persons Program Under MDUFMA; Accreditation Criteria.	68 F.R. 22400	Any time.
4/29/2003	Request for comments on proposed information collection — MedWatch: The FDA Medical Products Reporting Program. Also see also 2/2/2003 (60-day notice) and 10/10/2003 (OMB approval).	68 F.R. 22716	5/29/2003
4/30/2003	Reprocessed Single-Use Devices; Termination of Exemptions from Premarket Notification; Requirement for Submission of Validation Data. Provides list of critical reprocessed single-use devices whose exemption from 510(k) is terminated, and for which validation data is now required in a 510(k). Also see 6/26/2003 (adding nonelectric biopsy forceps to the list of critical reprocessed single-use devices whose exemption from 510(k) is terminated, and for which validation data is now required in a 510(k).).	68 F.R. 23139	Effective 4/30/2003; 510(k)s due 7/30/2004; validation data for devices already cleared under 510(k) due 1/30/2004
5/21/2003	Request for comments on proposed information collection — Medical Device User Fee Cover Sheet; Form FDA 3601. Also see 2/26/2003 (60-day notice) and 8/25/2003 (OMB approval).	68 F.R. 27818	6/30/2003
6/3/2003	Availability of Guidance — Pediatric Expertise for Advisory Panels.	68 F.R. 33166	Any time.
6/23/2003	Availability of Draft Guidance — Compliance with Section 301 of MDUFMA – Identification of Manufacturer of Medical Devices.	68 F.R. 37161	9/22/2003
6/26/2003	Announcement of OMB Approval of Information Collection; Inspection by Accredited Persons Program Under MDUFMA. This approval expires 9/30/2003. Also see 4/28/2003 (emergency submission to OMB).	68 F.R. 38065	—

DATE	SUBJECT	CITATION	COMMENT / ACTION DATE
6/26/2003	Reprocessed Single-Use Devices; Termination of Exemptions from Premarket Notification; Requirement for Submission of Validation Data. Adds nonelectric biopsy forceps to the list of critical reprocessed single-use devices whose exemption from 510(k) is terminated, and for which validation data is now required in a 510(k). Clarifies deadline dates shown in 4/30/2003 notice. Also see 4/30/2003 (original list of critical reprocessed single-use devices).	68 F.R. 38071	Effective 6/26/2003; 510(k)s due 9/27/2004.
7/8/2003	Agency Emergency Processing Under OMB Review; Submission of Validation Data for Reprocessed Single-Use Devices. Also see 8/28/2003 (OMB approval). • 7/23/2003 — Correction — Corrects OMB contact information. • 8/20/2003 — Correction — Corrects docket number cited in 7/23/2003 correction notice.	68 F.R. 40676 68 F.R. 43534 68 F.R. 50155	8/7/2003 — —
7/8/2003	Availability of Guidance — Validation Data in Premarket Notification Submissions [510(k)s] for Reprocessed Single-Use Medical Devices. • 7/23/2003 — Correction — Corrects docket number.	68 F.R. 40679 68 F.R. 43538	Any time. —
7/10/2003	Request for comments on proposed information collection — Inspection by Accredited Persons Program Under MDUFMA. (60-day notice.) Current information collection approval expires 9/30/2003; see 6/26/2003. *Not yet approved by OMB.*	68 F.R. 41160	9/8/2003
7/18/2003	Request for comments on proposed information collection — MDUFMA Small Business Qualification Certification (Form FDA 3602). (60-day notice.) Revised version for use during FY 2004. Also see 10/10/2003 (request for comments). *Not yet approved by OMB.*	68 F.R. 42742	9/16/2003
7/24/2003	Availability of Draft Guidance — Premarket Assessment of Pediatric Medical Devices.	68 F.R. 43729	10/23/2003
8/1/2003	Establishment of Medical Device User Fee Rates for Fiscal Year 2004.	68 F.R. 45246	—
8/25/2003	Announcement of OMB Approval of Information Collection; Medical Device User Fee Cover Sheet (Form FDA 3601). Approval expires 8/31/2006. Also see 2/26/2003 (60-day notice) and 5/21/2003 (request for comments).	68 F.R. 51023	—

DATE	SUBJECT	CITATION	COMMENT / ACTION DATE
8/28/2003	Announcement of OMB Approval of Information Collection; Submission of Validation Data for Reprocessed Single-Use Devices. Approval expires 1/31/2004. Also see 7/8/2003 (emergency submission to OMB).	68 F.R. 51788	—
9/29/2003	Notice of first Annual Stakeholder Meeting on Implementation of MDUFMA, to be held December 3, 2003.	68 F.R. 55967	Register to attend or listen (via call-in line) by 11/3/2003; indicate intent to speak and provide topic abstract by 11/3/2003.

Appendix H: Quantitative and Descriptive Measures

Performance on MDUFMA's goals and commitments is measured in two ways: quantitatively and descriptively. The following describes these two categories of performance measures.

Quantitative Measures. Quantitative progress is measured and described primarily through standard, quantifiable statistics (for example, number of submissions, mean performance, median performance, percent meeting a review time standard). Each quantitative goal has the following characteristics:

- a clear definition of the submissions to which the goal applies (e.g., expedited PMAs),
- a clear definition of the action FDA is to take (e.g., issue a first action major deficiency letter),
- an objective review time standard (i.e., the number of days or months within which FDA is expected to take action),
- a quantifiable measure of performance (i.e., the minimum percent of submissions for which FDA is expected to meet the review time standard), and
- a specific time frame within which the goal applies (i.e., the fiscal year for which FDA performance will be evaluated).

MDUFMA's review performance goal progress is measured using quantitative methods.[22] Most of these goals use measures of success that become significantly more challenging over time.[23] This approach recognizes that FDA must first hire and train new staff and rebuild review program infrastructures before it will be possible to make substantial progress in improving overall review performance, while providing interim goals that allow periodic evaluation of FDA's progress towards the ultimate goals of the program.

Descriptive Measures. MDUFMA's commitments use descriptive measures to assess performance.[24] For descriptive measures, progress is reported through narrative accounts outlining specific actions taken, in addition to any results attributed to those actions. Descriptive measures:

[22] These are defined in section I, paragraphs A through H, of FDA's commitment letter. A tabular summary of all of MDUFMA's objective performance goals is provided in Attachment C.

[23] For example, Section I, paragraph B, goal 3(a) of FDA's commitment letter sets the following goal for Expedited PMAs: "70% of submissions received in fiscal year 2005 will have an FDA decision in 300 days." This is a quantitative goal because it applies to a defined category of applications (expedited PMAs), involves a defined type of action (an FDA decision), sets an objective review time standard (300 days), has a quantifiable measure of successful performance (70% of submissions), and applies within a specific time frame (FY 2005).

[24] Defined in section I, paragraphs I through P, of FDA's commitment letter

- do not involve an objective review time standard
- do not have a quantifiable measure of successful performance, and
- do not specify the time frame within which it must be completed.

FDA regards all of MDUFMA's descriptive performance commitments to be in effect beginning with FY 2003 and will report progress towards achieving these commitments each year in the annual performance report.

This report was prepared by FDA's Office of Planning in collaboration with the Center for Biologics Evaluation and Research (CBER) and the Center for Devices and Radiological Health (CDRH). For information on obtaining additional copies contact:

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