FY 2005

PERFORMANCE REPORT TO CONGRESS

for the

Medical Device User Fee and Modernization Act of 2002

C|B
E|R
Center for Biologics Evaluation and Research

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Center for Devices and Radiological Health

Commissioner's Report

I am pleased to report that the Food and Drug Administration (FDA) continues to make good progress in implementing the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and that FDA's performance through FY 2005 is consistent with the comprehensive and challenging performance goals of MDUFMA.

MDUFMA requires close collaboration with stakeholders and increased communication with applicants. FDA is working to clarify its regulatory requirements and make its decisions more transparent through new guidance, educational materials, and meetings. We continually seek to reduce the burdens associated with device reviews and to improve the efficiency and flexibility of our review processes. These efforts help applicants improve the quality of their submissions, and help FDA provide more rapid, better-focused reviews. Our ultimate objective — an objective we believe we share with industry — is to make important new medical devices available to patients and health care providers earlier, while continuing to ensure the quality, safety, and effectiveness of those devices.

I am proud of the significant progress FDA has made in meeting the challenges and responsibilities provided by MDUFMA. I believe the results we have achieved through FY 2005, and the long-term objectives we continue to pursue, clearly demonstrate the value of this important legislation to FDA, to the medical device industry, and, particularly, to patients and health care professionals.

Andrew von Eschenbach, M.D.
Acting 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 (FD&C Act) to authorize the Food and Drug Administration (FDA) to collect user fees from manufacturers who submit certain applications to market medical devices. In exchange for this authority, MDUFMA requires that FDA pursue a comprehensive set of review performance goals and commitments to improve the timeliness and predictability of medical device reviews.

FDA has made good progress in implementing MDUFMA and is making satisfactory progress towards achieving the performance goals set under MDUFMA. FDA has worked hard to communicate the new requirements and challenges of MDUFMA to its stakeholders. FDA has worked with its stakeholders to ensure that the implementation of the new law proceeds smoothly. FDA is confident that the implementation of MDUFMA will result in significant benefits to industry, health care professionals, and, most importantly, patients.

FY 2005 Activities

FDA continued to focus on consulting with its stakeholders, developing guidance documents, and designing and building the new review processes and process improvements required to meet MDUFMA's challenging performance goals. Among the key activities during FY 2005 were:

- **Steady progress in meeting MDUFMA performance goals**. FDA is meeting, or is on track to meet, nearly all of the performance goals for FY 2003, FY 2004, and FY 2005 receipt cohorts.
- **Guidance to industry.** FDA issued six MDUFMA guidance documents during FY 2005; four provided new guidance and two provided updated editions of earlier guidance.
- **Stakeholder communication and consultation.** FDA expanded its outreach to stakeholders, providing additional information through the MDUFMA Internet site (http://www.fda.gov/cdrh/mdufma), through presentations at industry and professional meetings, and at quarterly meetings with stakeholders. In November 2004, FDA held its second Annual Stakeholder Meeting to report on the implementation of MDUFMA and to hear directly from stakeholders.
- **Public notification.** FDA published 13 *Federal Register* notices to provide essential information to stakeholders on new guidance documents, proposed rules, regulatory actions, user fees, and other topics, and to request comments and suggestions from stakeholders.

- **Reports to Congress.** FDA submitted reports to Congress on FDA's implementation of MDUFMA performance goals through FY 2004, MDUFMA finances through FY 2004, and on the operations of FDA's Office of Combination Products during FY 2004. The U.S. Government Accountability Office (GAO) also reported to Congress on FDA's implementation of MDUFMA.[1]
- **Effort applied to MDUFMA activities (the process for the review of device applications).**[2] During FY 2005, the Center for Devices and Radiological Health (CDRH) applied approximately 950 full-time equivalents (FTEs) to the process for the review of device applications, 135 FTEs more than FY 2004 and 220 FTEs more than FY 2002 (just prior to enactment of MDUFMA). During FY 2005, the Center for Biologics Evaluation and Research (CBER) applied approximately 80 FTEs, an increase of 14 FTEs over FY 2004 and approximately 33 FTEs over FY 2002.

Overall Performance

FDA's overall performance to date for the FY 2003, FY 2004, and FY 2005 receipt cohorts is consistent with the expectations for the device review program agreed to by FDA, industry stakeholders, and Congress. Of the 24 quantifiable performance goals that were in effect for the FY 2003 through FY 2005 cohorts, FDA's performance to date is meeting or exceeding 18 goals and is not meeting 3 goals; the remaining 3 goals have not yet had any actions to measure.[3]

[1] "Limited Available Data Indicate That FDA Has Been Meeting Some Goals for Review of Medical Device Applications" (GAO-05-1042).
[2] The "process for the review of device applications" is defined by section 737(5) of the FD&C Act.
[3] Results to date are subject to revision over time as FDA completes all action on the remaining open applications within each cohort.

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Introduction

> ***. . . prompt approval and clearance of safe and effective devices is critical to the improvement of the public health so that patients may enjoy the benefits of devices to diagnose, treat, and prevent disease*** *. . .*
>
> — Section 101(1) of the Medical Device User Fee and Modernization Act of 2002.

On October 26, 2002, MDUFMA was signed into law. MDUFMA amends the FD&C Act to authorize FDA to collect fees from companies who submit certain applications for marketing of medical devices. In return, MDUFMA requires FDA to pursue a comprehensive set of device review performance goals that are intended to significantly improve the timeliness and predictability of FDA's review of new devices.[4] These performance goals were developed collaboratively and are defined in the Department of Health and Human Services (HHS) Secretary Thompson's November 14, 2002, letter to Congress.[5] 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 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 report is FDA's third annual performance report on its progress in achieving MDUFMA's performance goals and additional commitments, and covers actions through FY 2005.

On April 1, 2004, MDUFMA was amended and expanded by the Medical Device Technical Corrections Act (MDTCA), P.L. 108-214. MDTCA amends MDUFMA to clarify Congress's intent and to improve and expand upon some features of MDUFMA. These changes did not affect the performance goals FDA is pursuing under MDUFMA.

On August 1, 2005, the Medical Device User Fee Stabilization Act of 2005 (the "Stabilization Act"), P.L. 109-43 amended provisions of the Federal Food, Drug, and Cosmetic Act relating to medical device user fees and device labeling. FDA has agreed to keep in place the specific performance goals defined in section I, paragraphs A through H of FDA's November 14, 2002, commitment letter to Congress.

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

[5] HHS 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.

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Overview of MDUFMA

Background

MDUFMA was signed into law on October 26, 2002, amending the FD&C 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 CDRH. However, a number of devices that are critical to ensuring the safety, purity, and potency of biologic products, including assuring the safety of our nation's supply of blood and human tissue products, are reviewed by 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 discusses the types of devices regulated by CBER (available at http://www.fda.gov/oc/ombudsman/bio-dev.htm).

MDUFMA Commitments: Goals and Approaches

This report is concerned primarily with the performance goals that are an integral part of MDUFMA. FDA has prepared a summary of MDUFMA, including information on topics not covered by this report; see http://www.fda.gov/cdrh/mdufma/mdufmasummary.pdf. FDA also prepares an annual financial report that provides information on review fee revenues and expenses and compliance with MDUFMA requirements concerning the collection and use of those fees; the current and past reports are available at http://www.fda.gov/oc/mdufma.

MDUFMA has three particularly significant provisions related to FDA performance:

- User fees for premarket reviews, including premarket approval applications (PMAs), product development protocols, premarket reports, biologics licensing applications (BLAs), certain supplements, and 510(k) premarket notifications. The revenues from these fees, and from additional appropriations, will allow FDA to pursue a set of performance goals that are intended to provide patients earlier access to safe and effective technology, and will provide more interactive and

rapid review to the medical device industry. An applicant that qualifies as a "small business" (gross receipts or sales of $100 million or less) may pay a reduced fee, and if the applicant has gross receipts or sales of $30 million or less, it may obtain a waiver of the fee for its *first* premarket application (PMA, BLA, product development protocol, or premarket report). 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 made 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 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 or by a health care professional.
- The sunset provision, which addresses how FDA is to determine the intended use of a device, is revoked.[6] The effect is to make the requirement permanent.
- The law now explicitly provides for modular review of PMAs.

Phased-In Performance Goals

Performance goals increased in number, complexity, and difficulty beginning in FY 2005. Few objectively-measurable goals were applied during FY 2003 and FY 2004, allowing FDA time to hire staff, build infrastructure, provide guidance to industry, and take other actions to implement the new law. More goals go into effect each year from FY 2006 through FY 2007, and the goals become more demanding each year. FDA must continually improve its processes and performance if it is to meet these performance goals (see Appendix C for an overview of MDUFMA's objectively-measurable performance goals).

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

MDUFMA Implementation

In addition to authorizing FDA to collect user fees for medical device applications, MDUFMA established review performance goals for FDA. These goals are intended to achieve progressive, year-by-year, improvements in review processes for medical devices. The performance goals recognized that FDA would need a 2-year start-up period (FY 2003 through FY 2004) to hire and train new staff and rebuild review program infrastructures before it would be possible to begin to make substantial progress in improving overall review performance. Consequently, most substantive review performance goals went into effect in FY 2005. User fees, coupled with additional appropriations from Congress, will help FDA more efficiently and more quickly make safe and effective medical devices available to the public.

FY 2005 Activities and Accomplishments

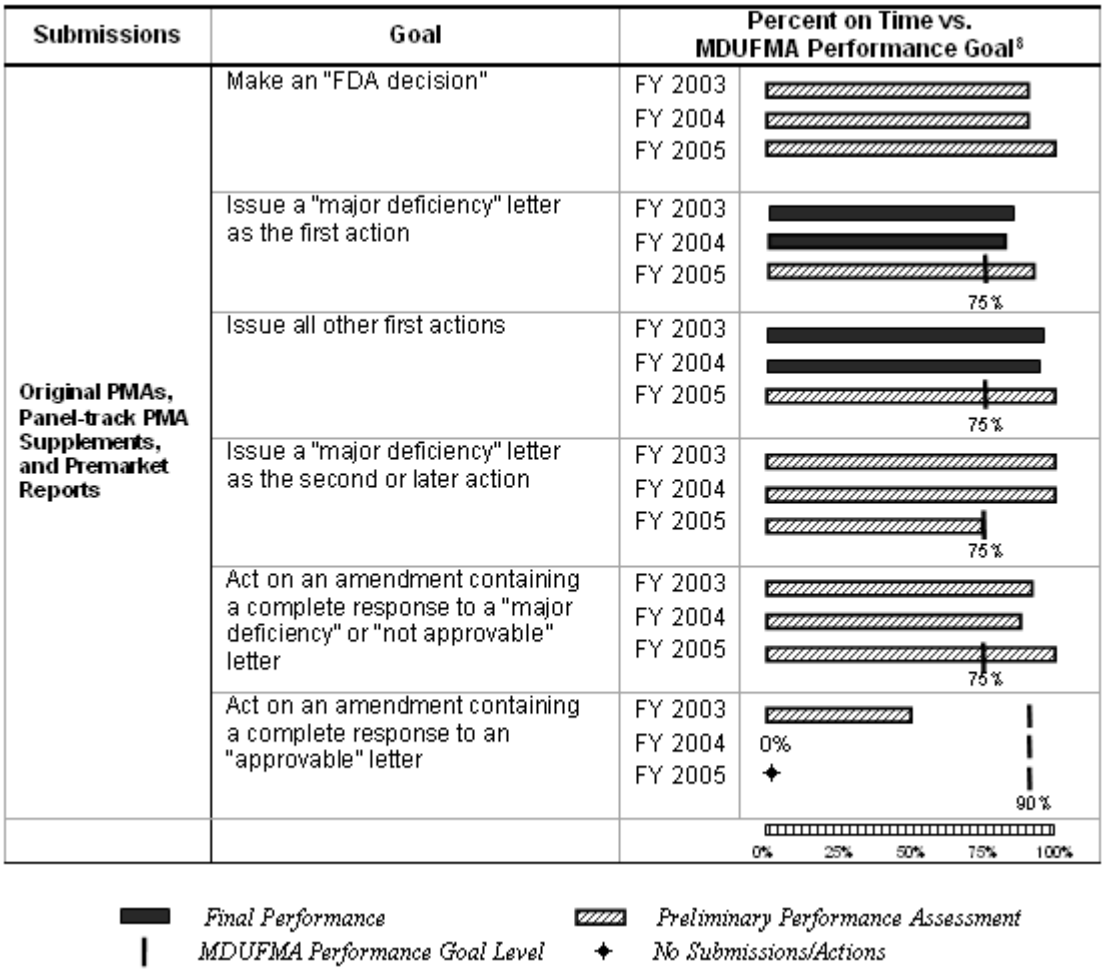
FDA made steady progress in implementing MDUFMA in FY 2005. FDA continued to focus on consulting with its stakeholders, developing guidance documents, and building the new review processes and process improvements required to meet MDUFMA's progressively challenging performance goals. Among the key activities and accomplishments during FY 2005 were:

- **Steady progress in meeting MDUFMA performance goals**. FDA is meeting, or is on track to meet, nearly all of the performance goals for FY 2003, FY 2004, and FY 2005 receipt cohorts.
- **Guidance documents.** FDA issued six MDUFMA guidance documents during FY 2005; four provided new guidance and two provided updated editions of earlier guidance.
    - Implementation of the Inspection by Accredited Persons Program Under The Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria (October 2004).
    - Resolution of Disputes Concerning Payment or Refund of Medical Device User Fees Under MDUFMA (November 2004).
    - Application User Fees for Combination Products (April 2005).
    - FY 2006 MDUFMA Small Business Qualification Worksheet and Certification (August 2005; replaces guidance for FY 2005).
    - How to Write a Request for Designation (RFD) (August 2005).
    - Requests for Inspection by an Accredited Person under the Inspection by Accredited Persons Program Authorized by Section 201 of the Medical Device User Fee and Modernization Act of 2002 (revised edition, September 2005).

- **Stakeholder communication and consultation.** FDA expanded its outreach to stakeholders, providing additional information through the MDUFMA Internet site (http://www.fda.gov/cdrh/mdufma), FDA presentations at industry and professional meetings, and quarterly meetings with stakeholders. In November 2004, FDA held its Annual Stakeholder Meeting to report on the implementation of MDUFMA and to hear directly from stakeholders.
- **Public notification.** FDA published 13 *Federal Register* notices to provide essential information to stakeholders on new guidance documents, proposed rules, regulatory actions, user fees, and other topics, and to also request comments and suggestions from stakeholders.
- **Reports to Congress**. FDA submitted reports to Congress on FDA's implementation of MDUFMA performance goals through FY 2004, MDUFMA finances through FY 2004, and on the operations of FDA's Office of Combination Products during FY 2004. In September 2005, the U.S. Government Accountability Office (GAO) also reported to Congress on FDA's implementation of MDUFMA.[1]
- **Effort applied to MDUFMA activities (the process for the review of device applications).** During FY 2005, the Center for Devices and Radiological Health (CDRH) applied approximately 950 full-time equivalents (FTEs) to the process for the review of device applications, 135 FTEs more than FY 2004, and 220 FTEs more than FY 2002 (just prior to enactment of MDUFMA). During FY 2005, the Center for Biologics Evaluation and Research (CBER) applied approximately 80 FTEs, an increase of 14 FTEs over FY 2004 and approximately 33 FTEs over FY 2002.

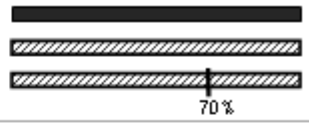
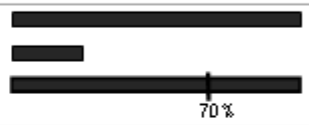
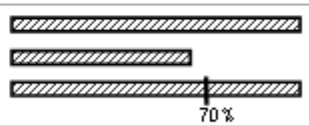
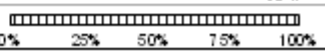
Overview of MDUFMA Performance, FY 2003 through FY 2005

A preliminary performance assessment from FY 2003 through FY 2005 indicates that FDA is meeting or exceeding most of the MDUFMA performance goals for submissions subject to MDUFMA goals (see table below). This assessment is based on data through September 30, 2005, and will be updated for each cohort on an annual basis.[7] The next section of this report, entitled "Report on FY 2005 MDUFMA Performance," presents a description of the review performance goals for each submission type, an overview of the workload, and an assessment of FDA's performance in meeting the goals.[8]

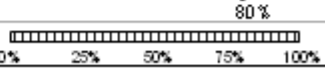


[7] All submissions under MDUFMA are measured by the cohort year of original submission. Until all submissions in a cohort are completed, only a preliminary performance assessment can be provided for that cohort.

[8] Most MDUFMA goals started in FY 2005 and the performance levels for the majority (approximately 85 percent) of the FY 2005 MDUFMA decision and cycle goals incrementally increase through FY 2007.

Submissions	Goal	Percent on Time vs. MDUFMA Performance Goal[8]
Expedited PMAs	Make an "FDA decision"	
	Issue a "major deficiency" letter as the first action	
	Issue all other first actions	
	Issue a "major deficiency" letter as the second or later action	
	Act on an amendment containing a complete response to a "major deficiency" or "not approvable" letter	
	Act on an amendment containing a complete response to an "approvable" letter	
		

Final Performance *Preliminary Performance Assessment*
MDUFMA Performance Goal Level *No Submissions/Actions*

Submissions	Goal	Percent on Time vs. MDUFMA Performance Goal[8]
180-day PMA Supplements	Make an "FDA decision"	
	Issue a "not approvable" letter as the first action	
	Issue all other first actions	
	Act on an amendment containing a complete response to a "not approvable" letter	
		

Final Performance *Preliminary Performance Assessment*
MDUFMA Performance Goal Level *No Submissions/Actions*

Submissions	Goal	Percent on Time vs. MDUFMA Performance Goal[8]
510(k)s	Make a "substantially equivalent" or "not substantially equivalent" decision	FY 2003 FY 2004 FY 2005 75%
	Issue an "additional information" letter as the first action	FY 2003 FY 2004 FY 2005 70%
	Issue any second or later action	FY 2003 FY 2004 FY 2005 70%
		0% 25% 50% 75% 100%

Final Performance — *Preliminary Performance Assessment*
MDUFMA Performance Goal Level — *No Submissions/Actions*

Submissions	Goal	Percent on Time vs. MDUFMA Performance Goal[8]
Original BLA and BLA Efficacy Supplement Resubmissions	Review and act on a "Class 1" resubmission	FY 2003 FY 2004 FY 2005 75%
	Review and act on a "Class 2" resubmission	FY 2003 FY 2004 FY 2005 75%
		0% 25% 50% 75% 100%

Final Performance — *Preliminary Performance Assessment*
MDUFMA Performance Goal Level — *No Submissions/Actions*

Implementation Plans for FY 2006

During FY 2005, FDA expanded its efforts, through employee hiring, training, guidance development, electronic tracking/review system expansion, and outreach, to improve the timeliness and efficiency of medical device review programs and build FDA's capacity to meet the more challenging goals set for FY 2006 and FY 2007. Among the key MDUFMA activities scheduled for FY 2006 are:

- **Increased performance expectations.** During FY 2006, six additional MDUFMA performance goals will go into effect, including goals for FDA decisions on PMAs and panel-track PMA supplements and all of the review goals for BLAs, BLA efficacy supplements, and BLA manufacturing supplements that require prior approval. Sixteen current performance goals will have higher performance level thresholds. Only two FY 2006 goals will have the same performance expectations as FY 2005.
- **Modular reviews**. The modular review program, currently restricted to premarket applications, will be extended to panel-track PMA supplements, and FDA will work with stakeholders to develop performance goals for modular reviews.
- **Pre-approval inspections.** FDA will issue guidance explaining how pre-approval inspections may be completed in considerably less time.
- **Guidances.** FDA will provide more substantive guidance on how third-party inspections are to be conducted. Additional guidance documents will be prepared; information on these and other efforts will be available on FDA's MDUFMA Internet site at http://www.fda.gov/cdrh/mdufma.
- "**Follow-on" licensed devices**. FDA will determine whether it is feasible to identify a category of "follow-on" licensed devices. If it is feasible to identify "follow-on" licensed devices, FDA will then determine whether specific performance goals appear to be appropriate for the review of such devices. If specific performance goals are appropriate, FDA will work with stakeholders to define and implement appropriate goals for reviews.

Report on FY 2005 MDUFMA Performance

This report presents FDA's performance on MDUFMA performance goals and commitments in FY 2005. Additionally, performance information presented in FDA's previous MDUFMA performance reports has been updated to include additional actions FDA completed during FY 2005. All performance data in this section reflects all FDA actions through September 30, 2005.

Performance goals. MDUFMA requires that FDA meet 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.

  Example: One of the goals for Expedited PMAs in the FY 2005 receipt cohort calls for FDA to issue 70 percent of "first action major deficiency letters" 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 major deficiency letter.

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

  Example: One of the goals for 510(k) premarket notifications in the FY 2005 receipt cohort calls for FDA to make 70 percent of "FDA decisions" within 90 days. FDA decisions for 510(k)s are "substantially equivalent" (SE) and "not substantially equivalent" (NSE) decisions. An SE or NSE decision ends the 510(k) review process.

Additional 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,[9] and examination of FDA's bundling policy.[10]

[9] See section I, paragraph L of FDA's Commitment Letter in Appendix A.
[10] See section I, paragraph N of FDA's Commitment Letter in Appendix A.

Measuring performance.[11] 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 are used to capture FDA's progress on meeting MDUFMA's performance goals and commitments:

- **Quantitative measures**. MDUFMA's performance goals (cycle and decision goals) 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, and percent meeting a review time standard).
- **Descriptive measures.** Alternatively, some MDUFMA commitments are more descriptive in nature. For example, progress is reported through narrative accounts outlining specific actions taken, in addition to any results attributed to those actions.

Receipt cohort. Review performance statistics are based on a receipt cohort. This methodology calculates performance statistics for the year submissions were received, regardless of when FDA acted on the submissions. A result 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 continues to complete work on 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 receive a final decision, only a preliminary performance assessment can be provided for that cohort.

[11] See Appendix B for a more detailed description of performance measures.

Premarket Approval Applications (PMAs), Panel-track PMA Supplements, and Premarket Reports

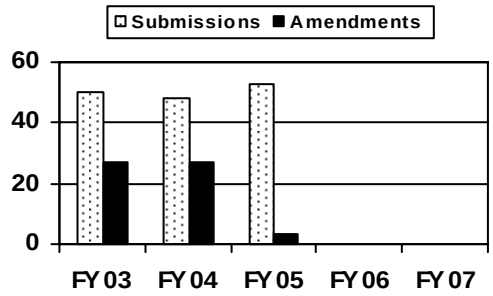
Goals

The table below summarizes the annual review time goals for Premarket Approval Applications (PMAs), Panel-track PMA supplements, and Premarket Reports. In FY 2003, the cycle goal of reviewing 90 percent of amendments containing a complete response to an "approvable" letter within 30 days became effective. Four additional cycle goals became effective in FY 2005 with the performance levels increasing incrementally through FY 2007. One new decision goal will become effective in FY 2006.

Goals		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%				

Workload

The total number of PMA and Panel-track PMA supplements submitted in FY 2005 increased, reaching a three-year high.[12] The total number of amendments to the FY 2003 and FY 2004 MDUFMA cohorts was the same (see graph to the right and table below).



PMAs, Panel-track PMA Supplements, and Premarket Reports					
Type	**FY 03**	**FY 04**	**FY 05**	**FY 06**	**FY 07**
Submissions	**50**	**48**	**53**	--	--
Amendments[13] *(major deficiency / approvable)*	**27** *(25/2)*	**27** *(26/1)*	**3** *(3/0)*	--	--

[12] FDA did not receive any Premarket Reports in FY 2003 through FY 2005.

[13] The limited number of amendments for the FY 2005 MDUFMA cohort is not a useful indicator for preliminary workload. Numbers are preliminary since amendments can still be submitted for FY 2003 through FY 2005 MDUFMA cohorts.

Premarket Approval Applications (PMAs), Panel-track PMA Supplements, and Premarket Reports

Performance

First Action Letters. FDA issued all first action letters for the FY 2003 and FY 2004 cohorts and over two-thirds (37 of 53) of first action letters for the FY 2005 cohort (see table below). Preliminary performance for the FY 2005 cohort indicates FDA is exceeding the MDUFMA performance goal for issuing a "major deficiency" as a first action (92 percent on time) and for issuing all other first action letters (100 percent on time).[14] With first action letters still pending, but not overdue as of September 30, 2005, it is too early to make a final performance determination.

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed	Percent on Time[15]	MDUFMA Performance Goal
Issue a "major deficiency" letter as the first action	150 days	2003	Y	22 / 26	85%	No Goal
		2004	Y	23 / 28	82%	No Goal
		2005	N	22 / 24	92%	75%
Issue all other first actions	180 days	2003	Y	23 / 24	96%	No Goal
		2004	Y	19 / 20	95%	No Goal
		2005	N	13 / 13	100%	75%

Second or Later Actions. FDA issued second or later actions for two submissions for the FY 2003 cohort and four each for the FY 2004 and FY 2005 cohorts (see table below). While FDA is meeting the MDUFMA performance goal for issuing a "major deficiency" letter as the second or later action based on the number of actions completed, the limited number of actions does not serve as a useful indicator for preliminary performance. FDA may still issue additional letters for the FY 2005 cohort; therefore, it is too early to make a final performance determination.

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed	Percent on Time	MDUFMA Performance Goal
Issue a "major deficiency" letter as the second or later action	120 days	2003	N	2 / 2	100%	No Goal
		2004	N	4 / 4	100%	No Goal
		2005	N	3 / 4	75%	75%

[14] No MDUFMA performance goal was in effect from FY 2003 to FY 2004.
[15] Final performance cannot be determined until cohort activity is completed.

Premarket Approval Applications (PMAs), Panel-track PMA Supplements, and Premarket Reports

Performance

Amendments. FDA reviewed and acted on all amendments received for the FY 2003 through FY 2005 MDUFMA cohorts (see table below).

"Major Deficiency" or "Not Approvable" Letters. Three amendments containing a complete response to a "major deficiency" or "not approvable" letter from the FY 2005 MDUFMA cohort were acted on within the review time. While FDA has met the MDUFMA performance goal based on the number of actions completed, the limited number of actions does not serve as a useful indicator for preliminary performance.

"Approvable" Letters. Two amendments containing a complete response to an "approvable" letter were acted on for the FY 2003 MDUFMA cohort, one for the FY 2004 MDUFMA cohort, and none were acted on for the FY 2005 MDUFMA cohort. While FDA has not met the MDUFMA performance goal based on the number of actions completed for the FY 2003 and FY 2004 cohorts, the limited number of actions does not serve as a useful indicator for preliminary performance.

FDA may still receive amendments for these cohorts; therefore, it is too early to make a final performance determination.

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed	Percent on Time	MDUFMA Performance Goal
Act on an amendment containing a complete response to a "major deficiency" or "not approvable" letter	180 days	2003	N	23 / 25	92%	No Goal
		2004	N	23 / 26	88%	No Goal
		2005	N	3 / 3	100%	75%
Act on an amendment containing a complete response to an "approvable" letter	30 days	2003	N	1 / 2	50%	90%
		2004	N	0 / 1	0%	90%
		2005	N	0 / 0	n/a	90%

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Expedited PMAs

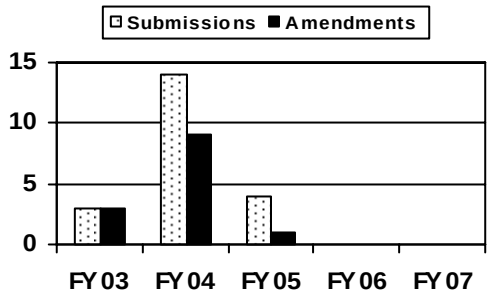
Goals

The table below summarizes the annual review time goals for Expedited PMAs. In FY 2003 the cycle goal of reviewing 90 percent of amendments containing a complete response to an "approvable" letter within 30 days became effective. One decision goal and four additional cycle goals became effective in FY 2005 with the performance levels increasing incrementally through FY 2007.

Goals		Review Time Goal	Performance Level				
			FY 03	FY 04	FY 05	FY 06	FY 07
Decision	Make an "FDA decision"	300 days	No Goal		70%	80%	90%
Cycle	Issue a "major deficiency" letter as the first action	120 days	No Goal		70%	80%	90%
	Issue all other first actions	170 days	No Goal		70%	80%	90%
	Issue a "major deficiency" letter as the second or later action	100 days	No Goal		70%	80%	90%
	Act on an amendment containing a complete response to a "major deficiency" or "not approvable" letter	170 days	No Goal		70%	80%	90%
	Act on an amendment containing a complete response to an "approvable" letter	30 days	90%				

Workload

The total number of Expedited PMA submissions received in FY 2005 decreased, returning to the FY 2003 level. The total number of amendments to the FY 2004 MDUFMA cohort is three times as many as the FY 2003 cohort (see graph to the right and table below).



Expedited PMAs					
Type	**FY 03**	**FY 04**	**FY 05**	**FY 06**	**FY 07**
Submissions	**3**	**14**	**4**	--	--
Amendments *(major deficiency / approvable)*	**3** ***(2 /1)***	**9** ***(8/1)***	**1** ***(1/0)***	--	--

Expedited PMAs

Performance

Decisions. FDA made decisions on all of the FY 2003 cohort, most (11 of 14) of the FY 2004 cohort, and half (2 of 4) of the FY 2005 MDUFMA cohort. While FDA is meeting the MDUFMA performance goal for making an "FDA decision", the limited number of actions does not serve as a useful indicator for preliminary performance (see table below). With decisions still pending, but not overdue as of September 30, 2005, it is too early to make a final performance determination.

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed	Percent on Time	MDUFMA Performance Goal
Make an "FDA decision"	300 days	2003	Y	3 / 3	100%	No Goal
		2004	N	11 / 11	100%	No Goal
		2005	N	2 / 2	100%	70%

First Action Letters. FDA issued all first action letters for the FY 2003, FY 2004, and FY 2005 cohorts (see table below). While FDA did not meet the MDUFMA performance goal for issuing a "major deficiency" letter as the first action and has met the MDUFMA performance for issuing all other first actions, the limited number of actions in the cohort limits the usefulness of these indicators for assessing performance for the FY 2005 cohort.

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed	Percent on Time	MDUFMA Performance Goal
Issue a "major deficiency" letter as the first action	120 days	2003	Y	2 / 2	100%	No Goal
		2004	Y	8 / 10	80%	No Goal
		2005	Y	2 / 3	67%	70%
Issue all other first actions	170 days	2003	Y	1 / 1	100%	No Goal
		2004	Y	1 / 4	25%	No Goal
		2005	Y	1 / 1	100%	70%

Expedited PMAs

Performance

Second or Later Action Letters. FDA did not issue any second or later action letters for the FY 2003 cohort, one for the FY 2004 cohort, and none for the FY 2005 cohort (see table below). FDA may still issue additional letters for the FY 2005 cohort; therefore, it is too early to make a final performance determination.

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed	Percent on Time	MDUFMA Performance Goal
Issue a "major deficiency" letter as the second or later action	100 days	2003	N	0 / 0	n/a	No Goal
		2004	N	0 / 1	0%	No Goal
		2005	N	0 / 0	n/a	70%

Amendments. FDA reviewed and acted on all amendments received for the FY 2003 through FY 2005 MDUFMA cohorts (see table below).

"Major Deficiency" or "Not Approvable" Letters. One amendment containing a complete response to a "major deficiency" or "not approvable" letter from the FY 2005 MDUFMA cohort was acted on within the review time. While FDA is meeting the MDUFMA performance goal based on the number of actions completed, the limited number of actions does not serve as a useful indicator for preliminary performance.

"Approvable" Letters. One amendment containing a complete response to an "approvable" letter was acted on for the FY 2003 MDUFMA cohort, one was acted on for the FY 2004 MDUFMA cohort, and none for the FY 2005 MDUFMA cohort. While FDA is meeting the MDUFMA performance goal based on the number of actions completed for the FY 2003 and FY 2004 cohorts, the limited number of actions does not serve as a useful indicator for preliminary performance.

FDA may still receive amendments for these cohorts; therefore, it is too early to make a final performance determination.

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed	Percent on Time	MDUFMA Performance Goal
Act on an amendment containing a complete response to a "major deficiency" or "not approvable" letter	170 days	2003	N	2 / 2	100%	No Goal
		2004	N	5 / 8	62%	No Goal
		2005	N	1 / 1	100%	70%
Act on an amendment containing a complete response to an "approvable" letter	30 days	2003	N	1 / 1	100%	90%
		2004	N	1 / 1	100%	90%
		2005	N	0 / 0	n/a	90%

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180-Day PMA Supplements

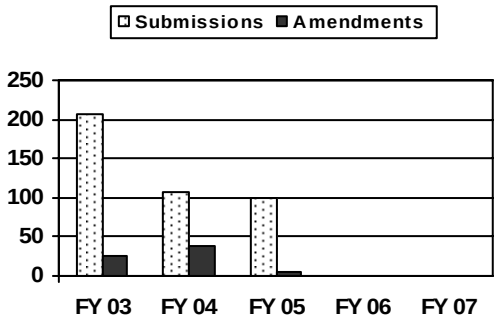
Goals

The table below summarizes the annual review time goals for 180-day PMA Supplements. One decision goal and three cycle goals became effective in FY 2005 with the performance levels increasing from 80 percent in FY 2005 to 90 percent in FY 2007.

Goals		Review Time Goal	Performance Level				
			FY 03	FY 04	FY 05	FY 06	FY 07
Decision	Make an "FDA decision"	180 days	No Goal		80%	80%	90%
Cycle	Issue a "not approvable" letter as the first action	120 days	No Goal		80%	85%	90%
	Issue all other first actions	180 days	No Goal		80%	85%	90%
	Act on an amendment containing a complete response to a "not approvable" letter	160 days	No Goal		80%	85%	90%

Workload

The total number of 180-day PMA supplements received in FY 2004 and FY 2005 decreased by almost one-half when compared to the FY 2003 level. The number of amendments to the FY 2004 cohort increased by approximately 50 percent as compared to the FY 2003 cohort (see graph to the right and table below).



180-day PMA Supplements					
Type	FY 03	FY 04	FY 05	FY 06	FY 07
Submissions	206	106	99	--	--
Amendments	25	38	6	--	--

180-Day PMA Supplements

Performance

Decisions. FDA made decisions on all of the FY 2003 and FY 2004 cohort submissions and on two-thirds (65 of 99) of the FY 2005 MDUFMA cohort (see table below). Preliminary performance for the FY 2005 cohort indicates FDA is exceeding the MDUFMA performance goal for making an "FDA decision" (97 percent on time) (see table below). With decisions still pending, but not overdue as of September 30, 2005, it is too early to make a final performance determination.

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed	Percent on Time	MDUFMA Performance Goal
Make an "FDA decision"	180 days	2003	Y	194 / 206	94%	No Goal
		2004	Y	102 / 106	96%	No Goal
		2005	N	63 / 65	97%	80%

First Action Letters. FDA issued all first action letters for the FY 2003 and FY 2004 cohorts and over two-thirds (68 of 99) of first action letters for the FY 2005 cohort (see table below). Preliminary performance for the FY 2005 cohort indicates FDA is exceeding the MDUFMA performance goal for issuing a "not approvable" letter as a first action (92 percent on time) and for issuing all other first action letters (98 percent on time). With first action letters still pending, but not overdue as of September 30, 2005, it is too early to make a final performance determination.

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed	Percent on Time	MDUFMA Performance Goal
Issue a "not approvable" letter as the first action	120 days	2003	Y	6 / 32	19%	No Goal
		2004	Y	36 / 43	84%	No Goal
		2005	N	24 / 26	92%	80%
Issue all other first actions	180 days	2003	Y	166 / 174	95%	No Goal
		2004	Y	61 / 63	97%	No Goal
		2005	N	41 / 42	98%	80%

180-Day PMA Supplements

Performance

Amendments. FDA reviewed and acted on all amendments received for the FY 2003 through FY 2005 MDUFMA cohorts (see table below).

"Not Approvable" Letters. Six amendments containing a complete response to a "not approvable" letter from the FY 2005 cohort were acted on within the review time. While FDA is meeting the MDUFMA performance goal based on the number of actions completed, the limited number of actions does not serve as a useful indicator for preliminary performance.

FDA may still receive amendments for these cohorts; therefore, it is too early to make a final performance determination.

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed	Percent on Time	MDUFMA Performance Goal
Act on an amendment containing a complete response to a "not approvable" letter	160 days	2003	N	24 / 25	96%	No Goal
		2004	N	38 / 38	100%	No Goal
		2005	N	6 / 6	100%	80%

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510(k) Premarket Notifications

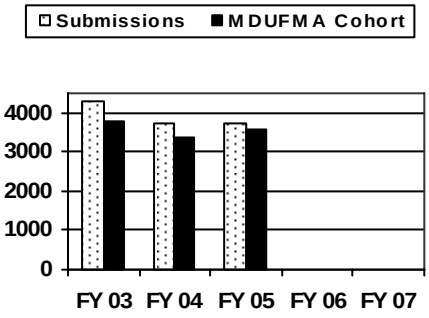
Goals

The table below summarizes the annual review time goals for 510(k) Premarket Notifications. One decision goal and two cycle goals became effective in FY 2005. The performance level for the decision goal remains constant at 75 percent for FY 2005 and FY 2006 and increases to 80 percent in FY 2007.[16] The performance levels for the two cycle goals increase incrementally from 70 percent in FY 2005 to 90 percent in FY 2007.

Goals		Review Time Goal	Performance Level				
			FY 03	FY 04	FY 05	FY 06	FY 07
Decision	Make a "substantially equivalent" or "not substantially equivalent" decision	90 days	No Goal		75%		80%
Cycle	Issue an "additional information" letter as the first action	75 days	No Goal		70%	80%	90%
	Issue any second or later action	60 days	No Goal		70%	80%	90%

Workload

The total number of 510(k) submissions received in FY 2005 was virtually the same as FY 2004 (see graph to the right and table below).



510(k) Premarket Notifications					
Type	**FY 03**	**FY 04**	**FY 05**	**FY 06**	**FY 07**
Submissions	**4,290**	**3,710**	**3,712**	--	--
MDUFMA Cohort[17]	**3,801**	**3,388**	**3,573**	--	--

[16] FDA will re-evaluate the implementation of the FY 2007 goal during FY 2006. If FDA determines that the goal is not appropriate, prior to August 1, 2006, the Secretary will send a letter to the appropriate committees stating that the goal will not be implemented and the rationale for its removal, and that the goal for FY 2006 will be implemented for FY 2007 (see section I, paragraph D.3. of FDA's Commitment Letter in Appendix A).

[17] The MDUFMA Cohort for 510(k)s excludes submissions that were closed for any reason other than an SE or NSE decision (for example, when FDA finds that a 510(k) was not required). This number is subject to change until the cohort is closed.

510(k) Premarket Notifications

Performance

Decisions. FDA has made decisions on almost all of the FY 2003 MDUFMA cohort (3,795 of 3,801) and FY 2004 MDUFMA cohort (3,371 of 3,388), and over two-thirds (2,516 of 3,573) of the FY 2005 MDUFMA cohort (see table below). Preliminary performance for the FY 2005 MDUFMA cohort indicates FDA is exceeding the MDUFMA performance goal for making a "substantially equivalent" or "not substantially equivalent" decision (95 percent on time). With decisions still pending, but not overdue as of September 30, 2005, it is too early to make a final performance determination.

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed	Percent on Time	MDUFMA Performance Goal
Make a "substantially equivalent" or "not substantially equivalent" decision	90 days	2003	N	2,887 / 3,795	76%	No Goal
		2004	N	2,835 / 3,371	84%	No Goal
		2005	N	2,400 / 2,516	95%	75%

First Action Letters. FDA issued almost half of the first action letters for the FY 2003 (1,719 of 3,801), FY 2004 (1,618 of 3,388), and FY 2005 (1,573 of 3,573) MDUFMA cohorts (see table below). Preliminary performance for the FY 2005 MDUFMA cohort indicates FDA is exceeding the MDUFMA performance goal for issuing an "additional information" letter as a first action (95 percent on time). With first action letters still pending, but not overdue as of September 30, 2005, it is too early to make a final performance determination.

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed	Percent on Time	MDUFMA Performance Goal
Issue an "additional information" letter as the first action	75 days	2003	N	1,005 / 1,719	58%	No Goal
		2004	N	1,271 / 1,618	79%	No Goal
		2005	N	1,490 / 1,573	95%	70%

510(k) Premarket Notifications

Performance

Second or Later Action Letters. FDA issued 611 second or later action letters for the FY 2003 MDUFMA cohort, 584 for the FY 2004 MDUFMA cohort, and 362 for the FY 2005 MDUFMA cohort (see table below). Preliminary performance for the FY 2005 cohort indicates FDA is exceeding the MDUFMA performance goal for issuing second or later action letters (94 percent on time). With the FY 2005 MDUFMA cohort still active as of September 30, 2005, second or later action letters are still possible. Therefore, it is too early to make a final performance determination for second or later action letters.

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed	Percent on Time	MDUFMA Performance Goal
Issue any second or later action	60 days	2003	N	311 / 611	51%	No Goal
		2004	N	478 / 584	82%	No Goal
		2005	N	340 / 362	94%	70%

Resubmitted BLAs and BLA Efficacy Supplements

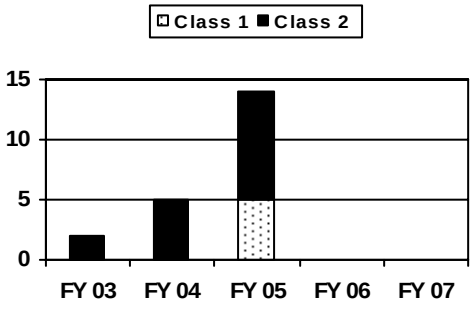
Goals

The table below summarizes two new annual review time goals for Resubmitted Original BLAs and BLA Efficacy Supplements for FY 2005 MDUFMA performance levels for the "Class 1" and "Class 2" resubmissions. Performance levels increase incrementally from 75 percent in FY 2005 to 90 percent in FY 2007.

Goals	Review Time Goal	Performance Level				
		FY 03	FY 04	FY 05	FY 06	FY 07
Review and act on "Class 1" original BLA and BLA efficacy supplement resubmissions	2 months	No Goals		75%	80%	90%
Review and act on "Class 2" original BLA and BLA efficacy supplement resubmissions	6 months	No Goals		75%	80%	90%

Workload

The total number of resubmitted BLAs and BLA efficacy supplement applications increased in FY 2005. "Class 1" resubmissions were received for the first time in three years while "Class 2" resubmissions almost doubled (see graph to the right and table below).



Resubmitted BLAs and BLA Efficacy Supplements					
Type	FY 03	FY 04	FY 05	FY 06	FY 07
"Class 1"	0	0	5	--	--
"Class 2"	2	5	9	--	--
MDUFMA Total	2	5	14	--	--

Resubmitted BLAs and BLA Efficacy Supplements

Performance

Resubmissions. FDA reviewed and acted on all of the resubmitted "Class 1" BLAs and BLA efficacy supplements for the FY 2005 cohort; there were no "Class 1" resubmissions received in FY 2003 and FY 2004 (see table below). FDA reviewed and acted on all resubmitted "Class 2" BLAs and BLA efficacy supplements for the FY 2003 and FY 2004 cohorts and two-thirds (6 of 9) of the FY 2005 cohort.

While FDA met the MDUFMA performance goal based on the number of actions completed for the "Class 1" resubmissions and is meeting the MDUFMA performance goal for the "Class 2" resubmissions, the limited number of actions does not serve as a useful indicator for preliminary performance. With "Class 2" resubmissions still pending, it is too early to make a final performance determination.

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed	Percent on Time	MDUFMA Performance Goal
Review and act on "Class 1" original BLA and BLA efficacy supplement resubmissions	10 months	2003	Y	0 / 0	n/a	No Goal
		2004	Y	0 / 0	n/a	No Goal
		2005	Y	5 / 5	100%	75%
Review and act on "Class 2" original BLA and BLA efficacy supplement resubmissions	6 months	2003	Y	2 / 2	100%	No Goal
		2004	Y	4 / 5	80%	No Goal
		2005	N	6 / 6	100%	75%

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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).

Maintenance of Current Performance

During FY 2005, FDA's review performance for submissions that do not have specific MDUFMA performance goals continued to be comparable to FY 2002 performance (prior to enactment of MDUFMA).

CDRH Performance Indicators	FY 02	FY 03	FY 04	FY 05
HDEs - Filing to first action (average FDA days)	53	48	52	63
HDEs - Elapsed time to approval (average FDA days)	175	152	182	223
IDEs - FDA review time (average FDA days)	28	27	28	28
IDEs - Percent of decisions made within 30 days	99%	100%	100%	96%
IDE Amendments - FDA review time (average FDA days)	18	19	18	20
IDE Amendments - Percent of decisions made within 30 days	100%	100%	100%	98%
IDE Supplements - FDA review time (average FDA days)	20	19	19	19
IDE Supplements - Percent of decisions made within 30 days	100%	100%	100%	100%
CBER Performance Indicators	**FY 02**	**FY 03**	**FY 04**	**FY 05**
BLA Supplements (CBE/CBE-30) - Percent reviewed and acted on within 6 months	99%	97%	100%	100%
PMA Supplements (CBE) - Percent of decisions made within 180 days	100%	100%	100%	100%
PMA Supplements (135-day) - Percent of decisions made within 135 days	NR	100%	100%	100%
PMA Supplements (CBE-30) - Percent of decisions made within 30 days	67%	100%	100%	100%

KEY: HDEs-Humanitarian Device Exemptions; IDEs-Investigational Device Exemptions; BLA-Biologic License Application; PMA-Premarket Application; CBE-Changes Being Effected; NR-None Received

NOTE: Some reported measures may change over time, as additional actions are taken on open applications.

Meetings with Regulated Industry

FDA continues to encourage meetings as a particularly effective way to ensure that both FDA and applicants understand the clinical, scientific, and regulatory issues associated with new technologies. Pre-IDE and pre-PMA meetings have proven to be particularly beneficial and are used routinely by industry. During FY 2005, FDA participated in more than 1,300 premarket meetings with industry. The more formal types of meetings (agreement meetings, determination meeting, 100-day meetings) are not used as frequently by premarket applicants.

Resources Applied to MDUFMA Activities

During FY 2005, FDA applied approximately 1,104 full-time equivalents (FTEs) (1,034 direct FDA FTEs and 70 contractor FTEs) to the process for the review of device applications. The total for FY 2005 is 275 FTEs (205 direct FDA FTEs and 70 contractor FTEs) over FY 2002.

FDA's FY 2005 MDUFMA Financial Report to Congress will provide additional information on FDA's use of resources for the MDUFMA program.

Modular PMA Review Program

FDA issued initial guidance on modular PMA reviews in its 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*, on February 25, 2003. This guidance explained that the fee for a modular PMA submission was due upon submission of the *first module* (not just the "shell" that described the overall plan for the modular submission).

On November 23, 2003, FDA provided a more comprehensive guidance document, *Premarket Approval Application Modular Review*; this guidance provided industry and FDA staff with information regarding the modular review program and outlined the procedures for submitting and reviewing a modular PMA. As FDA gains more experience with the modular PMA process, it will consult with stakeholders to develop performance goals for this program.

Bundling Policy

After consulting with stakeholders, FDA determined that bundling is appropriate under certain circumstances. On February 25, 2003, FDA issued initial guidance describing general bundling principles in its 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.* This guidance explained that bundling may involve multiple devices or multiple indications for use in a single submission. On November 26, 2003, FDA provided a more comprehensive guidance document, *Bundling Multiple Devices or Multiple Indications in a Single Submission*. This guidance was intended to help industry and FDA staff

understand when bundling may be appropriate, when separate submissions should be considered, and provided numerous examples illustrating these bundling principles for both 510(k) and PMA applications. Interest in bundling has increased since MDUFMA was enacted, and FDA is now receiving more bundled submissions.

Electronic Review of Applications

FDA published *Guidance for Industry, Providing Regulatory Submissions to CBER in Electronic Format - Investigational New Drug Applications (INDs)* (March 26, 2002), which applies to investigational studies of devices, such as blood screening test kits, leading to a BLA. CBER contributed to guidance documents on electronic submissions in general, and received a number of electronic submissions for biologic (non-device) reviews. To date, CBER has not received electronic submissions of any medical device applications.

CBER continues to make a significant outreach effort to inform regulated industry of the process for electronic submissions. In particular, during all sponsor meetings, CBER informs applicants and potential applicants of the ability to submit electronic documents. In addition, CBER is making provisions for secure e-mail when not associated with an original electronic application.

CDRH is working with applicants to expand the use of electronic submissions, focusing first on increasing the use of electronic copies of applications. CDRH has initiated a "Turbo 510(k)" pilot in the Office of In-Vitro Diagnostics Device Evaluation and Safety, providing an electronic template for submission and review of *in vitro* diagnostic device 510(k)s, and will use the experience gained and lessons learned from this pilot as it moves forward with additional electronic initiatives.

Preapproval Inspections

During FY 2003, FDA began a comprehensive examination of factors affecting the timeliness and efficiency of the preapproval inspection process to determine how the process can be improved and what resources would be required to make those improvements. FDA is continuing to examine alternatives to improve the timeliness and efficiency of the process, and began to develop guidance to: 1) help industry better understand the preapproval inspection process, so they will be better prepared for their inspections; and 2) explain how the Centers will work with applicants, the Office of Regulatory Affairs, and with its field inspectors to improve the timeliness of preapproval inspections. The guidance will include clearly-defined milestones in the preapproval inspection process to help ensure more timely scheduling and completion of inspections.

FDA expects to issue its guidance on preapproval inspections during FY 2006.

Next Steps to Implement MDUFMA Successfully

FDA faces a number of critical implementation steps in meeting MDUFMA's performance goals which grow progressively more challenging each year through FY 2007. These include building critical infrastructure, hiring and training additional staff, making greater use of external expertise, and reengineering our review processes to provide for more timely and efficient device reviews. Additionally, FDA will work with stakeholders, the Administration, and Congress to ensure continued success of the device user fee program.

FDA needs to address the following implementation challenges to achieve the improvements promised by MDUFMA.

- Develop data systems that ensure each device review subject to a user fee is linked to the correct user fee payment and systems to measure FDA's review performance against the many goals established under MDUFMA. This will require new internal systems, as well as systems to link very different databases in FDA's Office of the Commissioner, CBER, and CDRH.
- Move forward with electronic application submission and review systems and processes.
- Continue to hire and train additional FDA scientists, engineers, statisticians, and other staff to: better distribute review workloads, expand the opportunity for meetings and other interaction with applicants, expand and update guidance documents used by applicants to prepare high-quality applications, and undertake the many additional efforts that will be required to meet or exceed MDUFMA's performance goals.
- Make appropriate use of external expertise to ensure timely action on medical device reviews that involve novel new technologies or unusual efforts.
- Ensure timely pre-approval inspections, both within the United States and abroad.
- Refine the processes for modular PMA reviews, and to work with stakeholders to develop meaningful performance goals for these reviews.
- Ensure that device reviews are completed in as few cycles as possible, thereby speeding the introduction of important new medical technologies and providing greater predictability in the reviews.

Appendix A: November 14, 2002, Commitment Letter from HHS 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 percent of submission received in fiscal year 2005; 80 percent of submissions received in fiscal year 2006; 90 percent 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 percent of submissions received in fiscal year 2006 will have an FDA decision in 320 days.

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

3. Subject to the following paragraph, 50 percent 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 percent 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 percent of submissions received in fiscal year 2005; 80 percent of submissions received in fiscal year 2006; 90 percent 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 percent of submissions received in fiscal year 2005 will have an FDA decision in 300 days.

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

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

4. 90 percent 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 percent of submissions in fiscal year 2005; 85 percent of submissions in fiscal year 2006; 90 percent 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.[18]

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

2. Decision Goals:

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

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

(c) 90 percent 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.

[18] 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 percent of submissions received in fiscal year 2005; 80 percent of submissions received in fiscal year 2006; 90 percent 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 percent of submissions received in fiscal years 2005 and 2006 will have an FDA decision in 90 days.

3. Subject to the following paragraph, 80 percent 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 percent of submissions received in fiscal year 2006; 90 percent 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 percent of submissions received in fiscal year 2006; 90 percent 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 percent of submissions received in fiscal year 2005; 80 percent of submissions received in fiscal year 2006; 90 percent 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 percent of submissions received in fiscal year 2006; 90 percent 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 percent 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: Measuring Performance Under MDUFMA

Different types of performance goals require different types of performance measures. FDA measures its success in meeting MDUFMA's goals and commitments in two ways: using *quantitative* measures and using *descriptive* measures, depending on how the objective for a particular performance goal is described in FDA's commitment letter. If the commitment letter provides an objective standard against which to measure our progress, we use quantitative measures. If the commitment letter does not provide an objective standard, FDA uses descriptive 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.[19] Most of these goals use measures of success that become significantly more challenging over time. 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.

[19] These quantitative goals 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. An example of a quantitative goal is for Expedited PMAs: "70 percent 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 percent of submissions), and applies within a specific time frame (FY 2005) (see section I, paragraph B, goal 3(a) of FDA's Commitment Letter in Appendix A).

Example: An example of where a performance goal is evaluated through quantitative measures is an Expedited PMA, received during FY 2005, when FDA's first action is a "major deficiency" letter. FDA will take that action (issue the letter) within 150 days of receipt of the Expedited PMA [(FDA Commitment Letter, section I, paragraph B, Item 2(a)].

Descriptive Measures

When quantitative measure cannot be used to evaluate FDA's progress in implementing a performance goal, the Agency uses descriptive measures to assess its performance. The Agency reports its progress in narrative accounts that outline the specific actions FDA has taken, the results are attributed to those actions.

MDUFMA's commitments use descriptive measures to assess performance.[20] For descriptive measures, progress is reported through narrative accounts outlining specific actions taken, in addition to any results attributed to those actions. Descriptive measures:

- 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.

Example: An example of where a performance goal is evaluated using descriptive measures is when FDA issues guidance on modular reviews under section 515(c)(3), and works with stakeholders to develop appropriate performance goals for the modular review program [(FDA Commitment Letter, section I, paragraph L].

Receipt Cohorts

FDA measures its performance against applications in a *receipt cohort*. This methodology records performance on a submission in the statistics for the year it was *received*, regardless of when FDA ultimately acted on, approved, or cleared that submission. 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 all work on more and more submissions. As more submissions are completed, the statistics for that year of receipt must be adjusted to reflect the new completions.

[20] Defined in section I, paragraphs I through P, of FDA's Commitment Letter (see Appendix A).

Eligible Submissions Under MDUFMA

The performance goals of MDUFMA do not apply to device submissions received prior to FY 2003. Although FDA will work diligently to improve review performance for *all* applications, regardless of when they were received, submissions received prior to FY 2003 will not be reflected in the *performance statistics* used to evaluate FDA's progress towards meeting MDUFMA's goals. 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.

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 HHS Secretary Thompson's November 14, 2002, Commitment Letter).

Activity	Review Time	Performance Level (by FY) (— indicates no quantitative goal)				
		2003	2004	2005	2006	2007
PMAs, Panel-Track Supplements, Premarket Reports						
• FDA decision (approval, approvable, approvable pending GMP inspection, not approvable, denial)	320 days	—	—	—	80%	90%
• FDA decision – median performance	180 days	—	—	—	—	50%[21]
• First action – "major deficiency" letter	150 days	—	—	75%	80%	90%
• First action – all other first actions (approval, approvable, approvable pending GMP inspection, not approvable, or denial)	180 days	—	—	75%	80%	90%
• Second or later action – "major deficiency" letter	120 days	—	—	75%	80%	90%
• Action on an amendment containing a complete response to a "major deficiency" or "not approvable" letter	180 days	—	—	75%	80%	90%
• Action on an amendment containing a complete response to an "approvable" letter	30 days	90%	90%	90%	90%	90%
Expedited PMAs These goals apply when FDA has granted expedited status; the applicant has attended a pre-filing meeting; manufacturing facilities are ready for inspection; and the PMA is substantively complete as defined at the pre-filing meeting.						
• FDA decision (approval, approvable, approvable pending GMP inspection, not approvable, denial)	300 days	—	—	70%	80%	90%
• First action – "major deficiency" letter	120 days	—	—	70%	80%	90%
• First action – all other first actions (approval, approvable, approvable pending GMP inspection, not approvable, or denial)	170 days	—	—	70%	80%	90%
• Second or later action – "major deficiency" letter	100 days	—	—	70%	80%	90%
• Action on an amendment containing a complete response to a "major deficiency" or "not approvable" letter	170 days	—	—	70%	80%	90%
• Action on an amendment containing a complete response to an "approvable" letter	30 days	90%	90%	90%	90%	90%

[21] This goal will be re-evaluated following the end of FY 2005. FDA will hold a public meeting to consult with its stakeholders and to determine whether this goal is appropriate for implementation in FY 2007. If FDA determines that a goal is not appropriate, prior to August 1, 2006, the Secretary will send a letter to the appropriate committees stating that the goal will not be implemented and the rationale for its removal (see section I, paragraph A.3. of FDA's Commitment Letter in Appendix A).

Activity	Review Time	Performance Level (by FY) (— indicates no quantitative goal)				
		2003	2004	2005	2006	2007
180-day PMA Supplements						
• FDA decision (approval, approvable, approvable pending GMP inspection, not approvable, denial)	180 days	—	—	80%	80%	90%
• First action – "not approvable" letter	120 days	—	—	80%	85%	90%
• First action – all other first actions (approval, approvable, approvable pending GMP inspection, or denial)	180 days	—	—	80%	85%	90%
• Action on an amendment containing a complete response to a "not approvable" letter	160 days	—	—	80%	85%	90%
510(k)s						
• FDA decision (SE/NSE)	90 days	—	—	75%	75%	80%[16]
• First action – "additional information" letter	75 days	—	—	70%	80%	90%
• Second or later action	60 days	—	—	70%	80%	90%
Biologics Licensing Applications - BLAs						
• Review and act on standard original BLAs (issue "complete action" letter)	10.0 months	—	—	—	75%	90%
• Review and act on priority original BLA submissions (issue "complete action" letter)	6.0 months	—	—	—	75%	90%
BLA Supplements						
• Review and act on standard BLA efficacy supplements (issue "complete action" letter)	10.0 months	—	—	—	75%	90%
• Review and act on priority BLA efficacy supplements (issue "complete action" letter)	6.0 months	—	—	—	75%	90%
• Review and act on BLA manufacturing supplements that require prior approval (issue "complete action" letter)	4.0 months	—	—	—	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	—	—	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	—	—	75%	80%	90%

Note: Definitions for the terms used here are provided in Section III of the FDA's Commitment Letter.

Appendix D: Glossary

Biologics License Application (BLA) – An application submitted when an applicant wishes to obtain marketing approval for a biological product. A priority BLA is a product that would, if approved, involve a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious or life-threatening disease. A nonpriority BLA is considered a standard BLA.

BLA Supplement – A supplemental application to an approved BLA requesting approval of a change to a licensed biological product. When the change has the substantial potential to affect the safety or effectiveness of the product, FDA approval is required prior to product distribution.

BLA Resubmission and BLA Efficacy Supplement Resubmission – A resubmission used to respond to a letter from FDA indicating that the information was deficient. For Class 1 resubmissions, the new information may include matters related to product labeling, safety updates, and other minor clarifying information. For Class 2 resubmissions, the new information could warrant presentation to an advisory committee or a reinspection of the manufacturer's device establishment.

Class – Each generic type of device is assigned to one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the device: Class I - General Controls, Class II - General Controls and Special Controls, and Class III - General Controls and Premarket Approval.

Humanitarian Device Exemption (HDE) – An application that is similar to a premarket application (PMA), but exempt from the effectiveness requirements of a PMA. An approved HDE authorizes marketing of a Humanitarian Use Device (HUD).

Investigational Device Exemption (IDE) – An IDE allows an investigational device to be used in a clinical study.

Premarket Approval Application (PMA) – An application providing scientific and medical data to show that a Class III medical device is reasonably safe and effective for its intended use.

Expedited PMA – A PMA application granted priority status because the medical device is intended to treat or diagnose a life-threatening or irreversibly debilitating disease or condition and to address an unmet medical need.

Modular Review Program for PMAs – A mechanism by which an applicant may submit preclinical data and manufacturing information for review while still collecting, compiling, and analyzing the clinical data. A modular PMA is a compilation of sections or "modules" submitted at different times that together become a complete application.

Panel-track PMA Supplement – A supplemental application to an approved PMA or premarket report that requests a significant change in design or performance of the device, or a new indication for use of the device, and for which clinical data are generally necessary to provide a reasonable assurance of safety and effectiveness.

180-day PMA Supplement – A supplemental application to an approved PMA or premarket report that typically requests approval of a significant change in aspects of a device, such as its design, specifications, or labeling, when demonstration of reasonable assurance of safety and effectiveness either does not require new clinical data or requires only limited clinical data.

Premarket Notification [510(k)] – An application that demonstrates that the medical device to be marketed is substantially equivalent (SE) to a legally-marketed device that was or is currently on the U.S. market.

- **Substantially Equivalent (SE)** – A device is substantially equivalent to a legally marketed device.
- **Not Substantially Equivalent (NSE)** – A device is not substantially equivalent to the already legally marketed device.

Premarket Report – A type of premarket application required for high-risk devices originally approved for a single use (that is, use on a single patient during a single procedure) that a manufacturer has reprocessed for additional use.

Product Development Protocol (PDP) – An alternative to a PMA, based on early consultation between the sponsor and FDA, that leads to a device development and testing plan acceptable to both parties. It minimizes the risk that the sponsor will pursue the development of a device that FDA will not approve.

Appendix E: Summary of Footnotes

[1] "Limited Available Data Indicate That FDA Has Been Meeting Some Goals for Review of Medical Device Applications" (GAO-05-1042).
[2] The "process for the review of device applications" is defined by section 737(5) of the FD&C Act.
[3] Results to date are subject to revision over time as FDA completes all action on the remaining open applications within each cohort.
[4] Section 738(g) of FD&C Act, as amended by MDUFMA. Except where noted, all statutory citations in this report are to the FD&C Act, as amended by MDUFMA.
[5] HHS 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.
[6] Applicable to section 513(i)(1)(E).
[7] All submissions under MDUFMA are measured by the cohort year of original submission. Until all submissions in a cohort are completed, only a preliminary performance assessment can be provided for that cohort.
[8] Most MDUFMA goals started in FY 2005 and the performance levels for the majority (approximately 85 percent) of the FY 2005 MDUFMA decision and cycle goals incrementally increase through FY 2007.
[9] See section I, paragraph L of FDA's Commitment Letter in Appendix A.
[10] See section I, paragraph N of FDA's Commitment Letter in Appendix A.
[11] See Appendix B for a more detailed description of performance measures.
[12] FDA did not receive any Premarket Reports in FY 2003 through FY 2005.
[13] The limited number of amendments for the FY 2005 MDUFMA cohort is not a useful indicator for preliminary workload. Numbers are preliminary since amendments can still be submitted for FY 2003 through FY 2005 MDUFMA cohorts.
[14] No MDUFMA performance goal was in effect from FY 2003 to FY 2004.
[15] Final performance cannot be determined until cohort activity is completed.
[16] FDA will re-evaluate the implementation of the FY 2007 goal during FY 2006. If FDA determines that the goal is not appropriate, prior to August 1, 2006, the Secretary will send a letter to the appropriate committees stating that the goal will not be implemented and the rationale for its removal, and that the goal for FY 2006 will be implemented for FY 2007 (see section I, paragraph D.3. of FDA's Commitment Letter in Appendix A).
[17] The MDUFMA Cohort for 510(k)s excludes submissions that were closed for any reason other than an SE or NSE decision (for example, when FDA finds that a 510(k) was not required). This number is subject to change until the cohort is closed.
[18] 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.
[19] These quantitative goals 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. An example of a quantitative goal is for Expedited PMAs: "70 percent 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 percent of submissions), and applies within a specific time frame (FY 2005) (see section I, paragraph B, goal 3(a) of FDA's Commitment Letter in Appendix A).
[20] Defined in section I, paragraphs I through P, of FDA's Commitment Letter (see Appendix A).
[21] This goal will be re-evaluated following the end of FY 2005. FDA will hold a public meeting to consult with its stakeholders and to determine whether this goal is appropriate for implementation in FY 2007. If FDA determines that a goal is not appropriate, prior to August 1, 2006, the Secretary will send a letter to the appropriate committees stating that the goal will not be implemented and the rationale for its removal (see section I, paragraph A.3. of FDA's Commitment Letter in Appendix A).

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Food and Drug Administration

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