FY 2006

PERFORMANCE REPORT TO CONGRESS

for the

Medical Device User Fee and Modernization Act of 2002

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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 succeed in improving the process for the review of device applications and meeting the performance goals established under the Medical Device User Fee and Modernization Act of 2002 (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 timelier, better-focused reviews. Our ultimate objective — an objective 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.

MDUFMA will come to an end on October 1, 2007. On that date, FDA's authority to collect and use medical device user fees sunsets, as directed by section 107 of MDUFMA. FDA is committed to working with stakeholders and Congress to ensure timely reauthorization.

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 2006, 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 C. von Eschenbach, M.D.
Commissioner of Food and Drugs

Executive Summary

MDUFMA amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) to authorize FDA to collect user fees from manufacturers who submit certain applications to market medical devices. In parallel with this authority, MDUFMA requires FDA to pursue a comprehensive set of review performance goals and commitments to improve the timeliness and predictability of medical device reviews and to improve communications between FDA and industry.

FDA has made good progress in implementing MDUFMA and in meeting MDUFMA performance goals. FDA has worked with stakeholders to improve communication and understanding of MDUFMA requirements and to ensure that implementation accomplishes MDUFMA objectives. The performance gains and improved predictability in review processes achieved under MDUFMA are leading to significant benefits to industry, health care professionals, and patients.

FY 2006 Activities

FDA continued to focus on consulting with its stakeholders, developing guidance documents, and designing and building the new review processes required to meet MDUFMA's challenging performance goals. Among the key activities during FY 2006 were:

- **Continued progress in meeting MDUFMA performance goals.** FDA is meeting, or is on track to meet, most of the performance goals for FY 2003 through FY 2006 receipt cohorts.
- **Guidance to industry.** FDA issued six MDUFMA guidance documents during FY 2006; four provided new guidance and two provided updated editions of earlier guidance.
- **Regulation of reprocessed single-use devices.** FDA issued *Federal Register* notices specifying when a manufacturer must submit validation data to FDA for a reprocessed single-use device.
- **Stakeholder communication and consultation.** FDA expanded its outreach to stakeholders, providing additional information through the MDUFMA Internet site at: http://www.fda.gov/cdrh/mdufma, through presentations at industry and professional meetings, and at quarterly meetings with stakeholders. In November 2005, FDA held its third Annual Stakeholder Meeting to report on the implementation of MDUFMA and to hear directly from stakeholders. In May 2006, FDA held a public meeting to discuss implementation of two contingent performance goals for FY 2007; FDA determined it was appropriate to implement both goals.

- **Public notification.** FDA published 14 *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.

Overall Performance

FDA's overall performance to date for the FY 2003 through FY 2006 receipt cohorts is consistent with the expectations for the device review program agreed to by FDA. Of the 50 quantifiable performance goals that were in effect for the FY 2003 through FY 2006 cohorts, FDA's performance to date includes meeting or exceeding 32 goals and not meeting 6 goals. The remaining 12 goals did not have measurable actions as of September 30, 2006.[1]

[1] Results are as of September 30, 2006, and are subject to revision over time as FDA completes additional actions 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.[2] These performance goals were developed collaboratively and are defined in the Department of Health and Human Services (HHS) Secretary's November 14, 2002, letter to Congress.[3] Information about MDUFMA, including the text of the amendments and the performance goals and procedures, can be found on FDA's web site 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 fourth annual performance report on its progress in achieving MDUFMA performance goals and additional commitments, and covers actions through FY 2006.

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 FD&C Act relating to medical device user fees and device labeling.

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[2] 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.

[3] HHS Secretary 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 the Center for Devices and Radiological Health (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 the Center for Biologics Evaluation and Research (CBER). Additionally, CBER regulates diagnostic tests for retroviruses, including HIV, as well as devices used in cell and gene therapies. An Intercenter Agreement between CBER and CDRH 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:

1. 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, allow FDA to

pursue a set of performance goals that are intended to provide patients earlier access to safe and effective technology, and 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.

2. Establishment inspections may be conducted by accredited persons (third parties), under carefully prescribed conditions.
3. 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) are 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.[4] 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 went into effect in FY 2006 and will again in FY 2007, with the goals becoming more demanding each year. FDA must continually improve its processes and performance if it is to meet these goals (see Appendix C for an overview of MDUFMA's objectively-measurable performance goals).

[4] 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 2006 Activities and Accomplishments

FDA made steady progress in implementing MDUFMA in FY 2006. FDA continued to focus on consulting with its stakeholders, developing guidance documents, and building the new review processes required to meet MDUFMA's progressively challenging performance goals. Among the key activities and accomplishments during FY 2006 were:

- **Steady progress in meeting MDUFMA performance goals**. FDA is meeting, or is on track to meet, most of the performance goals for FY 2003 through FY 2006 receipt cohorts.
- **Guidance documents.** FDA issued six MDUFMA guidance documents during FY 2006; four provided new guidance and two provided updated editions of earlier guidance.
    1. Validation Data in Premarket Notification Submissions [510(k)s] for Reprocessed Single-Use Medical Devices (revised edition, September 2006); http://www.fda.gov/cdrh/ode/guidance/1216.pdf.
    2. Early Development Considerations for Innovative Combination Products (September 2006); http://www.fda.gov/oc/combination/innovative.html.
    3. FY 2007 MDUFMA Small Business Qualification Worksheet and Certification (August 2006; replaces guidance for FY 2006); http://www.fda.gov/cdrh/mdufma/guidance/2006.pdf.
    4. Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended — Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices (May 2006; final guidance, replaces prior draft guidance); http://www.fda.gov/cdrh/comp/guidance/1217.html.
    5. The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations (June 2006); http://www.fda.gov/cdrh/comp/guidance/1566.pdf.

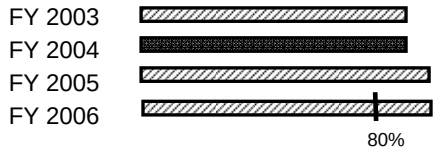
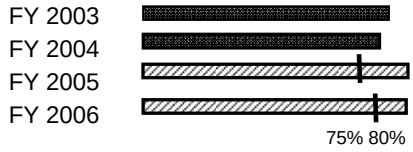
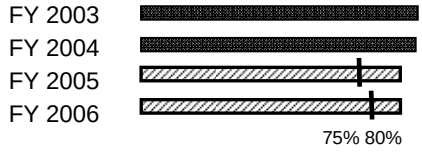
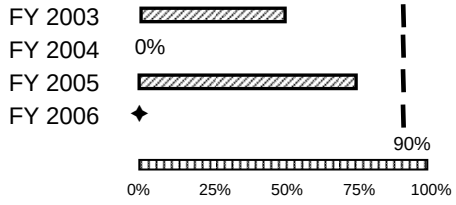
6. The Review and Inspection of Premarket Approval Applications under the Bioresearch Monitoring Program (June 2006); http://www.fda.gov/cdrh/comp/guidance/1602.pdf.

- **Stakeholder communications.** FDA held an annual stakeholder meeting on November 17, 2005, and a meeting on May 22, 2006, to discuss the possible implementation of the two contingent review performance goals for FY 2007. With stakeholder input, FDA decided to implement the two review performance goals for FY 2007: 1) 50 percent of the premarket approval applications received in FY 2007 will have an FDA decision in 180 days[5] and 2) 80 percent of the premarket notifications will have an FDA decision in 90 days.
- **Public notifications.** FDA issued 14 *Federal Register* notices in FY 2006.
- **Reports to Congress issued in FY 2006.** FDA issued to Congress the FY 2005 MDUFMA Performance Report, the FY 2005 MDUFMA Financial Report, and the FY 2005 Office of Combination Products Report.

[5] FDA and industry agree that, for FY 2007, FDA will manage its resources towards meeting the 180-day decision goal rather than the 150-day cycle goal for PMAs. FDA and industry understand that this focus on the 180-day decision goal may mean that FDA does not meet the 150-day cycle goal.

Overview of MDUFMA Performance, FY 2003 through FY 2006

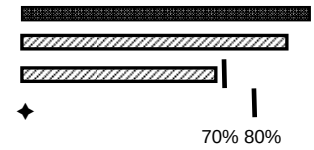
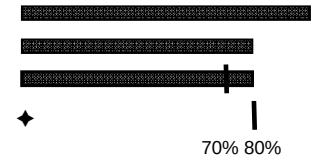
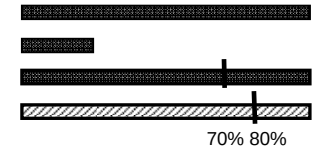
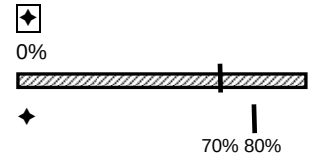
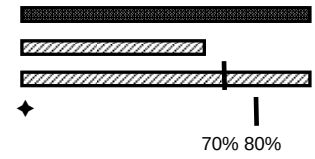
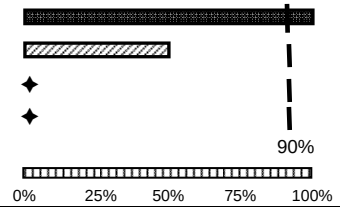
A preliminary performance assessment from FY 2003 through FY 2006 indicates that FDA is meeting or exceeding most of the MDUFMA performance goals for submissions subject to MDUFMA goals (see tables below). This assessment is based on data through September 30, 2006, and will be updated for each open cohort on an annual basis.[6]

Submissions	Goal	Percent on Time vs. MDUFMA Performance Goal[7]
Original PMAs, Panel-track PMA Supplements, and Premarket Reports	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	

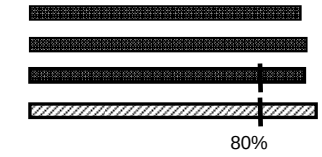
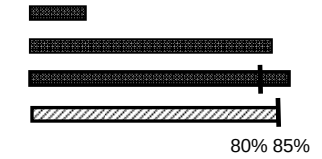
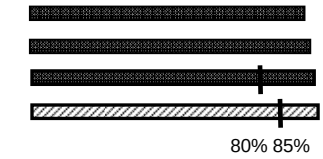
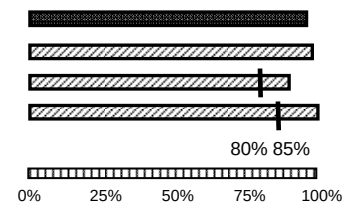
Final Performance — *Preliminary Performance Assessment*
MDUFMA Performance Goal Level — *No Submissions/Actions (Preliminary)*
No Submissions/Actions (Final)

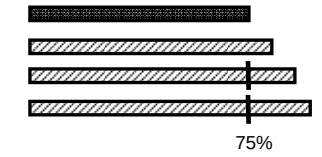
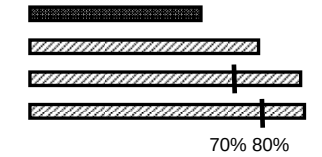
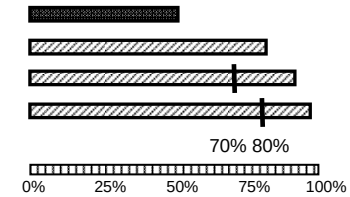
[6] All submissions under MDUFMA are measured by the cohort year of original submission. Until all submissions in a cohort are completed, only a preliminary performance assessment can be provided for that cohort.

[7] 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.

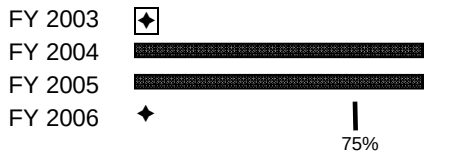
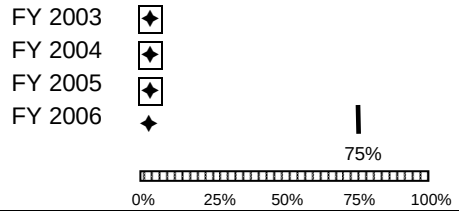
Submissions	Goal	Percent on Time vs. MDUFMA Performance Goal[7]
Expedited PMAs	Make an "FDA decision"	
	Issue a "major deficiency" letter as the first action	
	Issue all other first actions	
	Issue a "major deficiency" letter as the second or later action	
	Act on an amendment containing a complete response to a "major deficiency" or "not approvable" letter	
	Act on an amendment containing a complete response to an "approvable" letter	

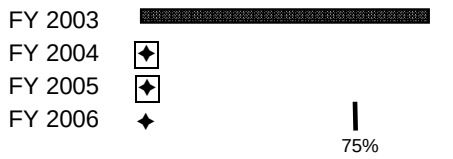
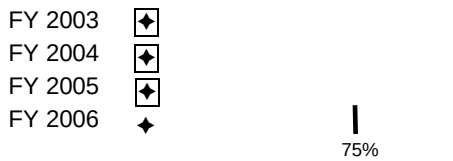
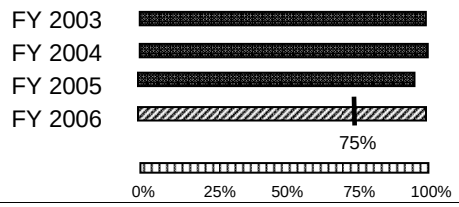
Final Performance *Preliminary Performance Assessment*
MDUFMA Performance Goal Level *No Submissions/Actions (Preliminary)*
No Submissions/Actions (Final)

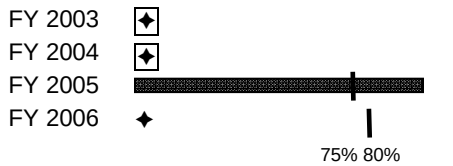
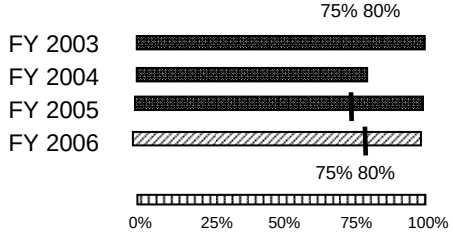
Submissions	Goal	Percent on Time vs. MDUFMA Performance Goal[7]
180-day PMA Supplements	Make an "FDA decision"	
	Issue a "not approvable" letter as the first action	
	Issue all other first actions	
	Act on an amendment containing a complete response to a "not approvable" letter	

Submissions	Goal	Percent on Time vs. MDUFMA Performance Goal[7]
510(k) Premarket Notifications	Make a "substantially equivalent" or "not substantially equivalent" decision	
	Issue an "additional information" letter as the first action	
	Issue any second or later action	

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

Submissions	Goal	Percent on Time vs. MDUFMA Performance Goal[7]
Biologics Licensing Applications - BLAs	Review and act on standard original BLAs (issue "complete action" letter)	
	Review and act on priority original BLAs (issue "complete action" letter)	

Submissions	Goal	Percent on Time vs. MDUFMA Performance Goal[7]
BLA Supplements	Review and act on standard BLA efficacy supplements (issue "complete action" letter)	
	Review and act on priority BLA efficacy supplements (issue "complete action" letter)	
	Review and act on BLA manufacturing supplements that require prior approval (issue "complete action" letter)	

Submissions	Goal	Percent on Time vs. MDUFMA Performance Goal[7]
Original BLA and BLA Efficacy Supplement Resubmissions	Review and act on a "Class 1" resubmission	
	Review and act on a "Class 2" resubmission	

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

Implementation Plans for FY 2007

During FY 2007, FDA will work to meet increased performance expectations, and to position the device review program to extend the performance improvements achieved under MDUFMA into FY 2008 and later years. The FY 2007 efforts for FDA will focus on:

- **Increased performance expectations.** FDA will implement a new goal for FY 2007 (50 percent of PMAs/panel-track PMA supplements received in FY 2007 are to have an "FDA decision" within 180 days).[5] Twenty-five goals will have higher performance levels for FY 2007. Two goals remain unchanged from FY 2006.
- "**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 those goals.
- **MDUFMA reauthorization.** FDA will consult with stakeholders on reauthorization of MDUFMA (the existing authority sunsets October 1, 2007), and will hold a public meeting to discuss recommendations for Congressional consideration. Reauthorization is critical to continued success of FDA's medical device review program.

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Report on FY 2006 MDUFMA Performance

This section presents FDA's preliminary performance on MDUFMA performance goals and commitments for FY 2006. Additionally, performance information between FY 2003 and FY 2005 presented in FDA's previous MDUFMA performance reports has been updated to include additional actions FDA completed during FY 2006. While performance is presented for all goals from FY 2003 through FY 2006, performance tables list "no goal" in fiscal years where no MDUFMA performance goal was in effect. All performance data in this section reflects FDA actions through September 30, 2006.

Performance goals. MDUFMA requires that FDA meet the following 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 and initiate a new cycle 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 that ends the review process.

  Example: One of the goals for 510(k) premarket notifications in the FY 2005 receipt cohort calls for FDA to make 75 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,[8] and examination of FDA's bundling policy.[9]

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

Measuring performance.[10] Progress on MDUFMA 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 performance goals and commitments:

- **Quantitative measures**. MDUFMA 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 fiscal 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 fiscal year may change from one report to the next. This is because as time passes, FDA continues to complete work on submissions within a fiscal year cohort. As more submissions are completed, the statistics for that fiscal 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. The word "cohort," as used in this section, refers to a MDUFMA fiscal year cohort.

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

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

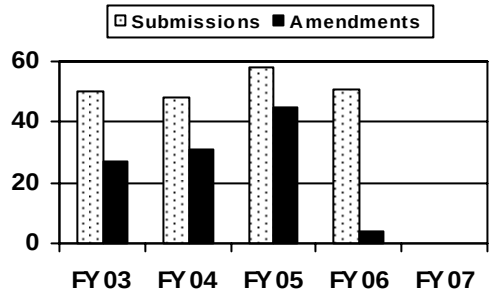
Goals

The table below summarizes the annual review time goals for 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. The decision goal became effective in FY 2006 with the performance levels increasing from 80 percent in FY 2006 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"	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 2006 decreased, returning to FY 2003 and FY 2004 levels.[11]



PMAs, Panel-track PMA Supplements, and Premarket Reports					
Type	**FY 03**	**FY 04**	**FY 05**	**FY 06**	**FY 07**
Submissions	**50**	**48**	**58**	**51**	--
Amendments[12] *(major deficiency / approvable)*	**27** *(25/2)*	**31** *(29/2)*	**45** *(37/8)*	**4** *(4/0)*	--

[11] FDA did not receive any premarket reports in FY 2003 through FY 2006.
[12] Additional amendments can still be submitted for cohorts not closed. In the FY 2005 MDUFMA Performance Report, the amendment numbers for FY 2003 through FY 2005 were 27, 27, and 3, respectively.

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

Performance

Decisions. FDA made decisions on over one-third (19 of 51) of the FY 2006 cohort. Preliminary numbers for the FY 2006 cohort indicate FDA is exceeding the MDUFMA performance goal for making an "FDA decision" (see table below).

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed	Percent on Time[13]	MDUFMA Performance Goal
Make an "FDA decision"	320 days	2003	N	44 / 48	92%	No Goal
		2004	Y	44 / 48	92%	No Goal
		2005	N	45 / 45	100%	No Goal
		2006	**N**	**19 / 19**	**100%**	**80%**

First Action Letters. FDA issued first action letters for all but one (57 of 58) of the FY 2005 cohorts and over four-fifths (42 of 51) of the FY 2006 cohorts. Preliminary numbers for the FY 2005 and FY 2006 cohorts indicate FDA is exceeding the MDUFMA performance goals for issuing a "major deficiency" letter as the first action and for issuing all other first action letters (see table below).

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed	Percent on Time[13]	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**	**34 / 37**	**92%**	**75%**
		2006	**N**	**20 / 22**	**91%**	**80%**
Issue all other first actions	180 days	2003	Y	23 / 24	96%	No Goal
		2004	Y	19 / 20	95%	No Goal
		2005	**N**	**18 / 20**	**90%**	**75%**
		2006	**N**	**18 / 20**	**90%**	**80%**

[13] Final performance cannot be determined until cohort activity is completed.

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

Performance

Second or Later Actions. Preliminary numbers for the FY 2005 cohort indicate FDA is not meeting the MDUFMA performance goal for issuing a "major deficiency" letter as the second or later action (see table below). Preliminary numbers for the FY 2006 cohort indicate that FDA is exceeding the MDUFMA performance goal.

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed	Percent on Time[13]	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**	**12 / 17**	**71%**	**75%**
		2006	**N**	**3 / 3**	**100%**	**80%**

Amendments. FDA reviewed and acted on all amendments received for the FY 2003 through FY 2006 cohorts. Preliminary numbers for the FY 2005 and FY 2006 cohorts indicate FDA is exceeding the MDUFMA performance goal for acting on an amendment containing a complete response to a "major deficiency" or "not approvable" letter (see table below). Preliminary numbers for the FY 2003 through FY 2005 cohorts indicate FDA is not meeting the MDUFMA performance goal for acting on an amendment containing a complete response to an "approvable" letter.

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed	Percent on Time[13]	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	26 / 29	90%	No Goal
		2005	**N**	**34 / 37**	**92%**	**75%**
		2006	**N**	**4 / 4**	**100%**	**80%**
Act on an amendment containing a complete response to an "approvable" letter	30 days	**2003**	**N**	**1 / 2**	**50%**	**90%**
		2004	**N**	**0 / 2**	**0%**	**90%**
		2005	**N**	**6 / 8**	**75%**	**90%**
		2006	**N**	**0 / 0**	**n/a**	**90%**

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Expedited PMAs

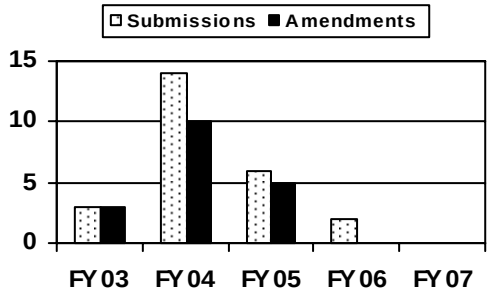
Goals

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. The decision goal and four additional cycle goals became effective in FY 2005 with the performance levels increasing 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 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 2006 continued to decrease from the FY 2004 high of 14, returning close to the FY 2003 level.



Expedited PMAs					
Type	**FY 03**	**FY 04**	**FY 05**	**FY 06**	**FY 07**
Submissions	**3**	**14**	**6**	**2**	--
Amendments[14] *(major deficiency / approvable)*	**3** *(2/1)*	**10** *(8/2)*	**5** *(5/0)*	**0** *(0/0)*	--

[14] Additional amendments can still be submitted for cohorts not closed. In the FY 2005 MDUFMA Performance Report, the amendment numbers for FY 2003 through FY 2005 were 3, 9, and 1, respectively.

Expedited PMAs

Performance

Decisions. FDA made decisions on half (3 of 6) of the FY 2005 cohort, and no actions were completed for the FY 2006 cohort. Preliminary numbers for the FY 2005 cohort indicate FDA is not meeting the MDUFMA performance goal for making an "FDA decision" (see table below).

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed	Percent on Time[13]	MDUFMA Performance Goal
Make an "FDA decision"	300 days	2003	Y	3 / 3	100%	No Goal
		2004	N	12 / 13	92%	No Goal
		2005	**N**	**2 / 3**	**67%**	**70%**
		2006	**N**	**0 / 0**	**n/a**	**80%**

First Action Letters. FDA issued first action letters for all of the FY 2005 cohorts and one of two for the FY 2006 cohorts. Final numbers for the FY 2005 cohorts indicate FDA exceeded the MDUFMA performance goals for issuing a "major deficiency" letter as the first action and for issuing all other first action letters (see table below). Preliminary numbers for the FY 2006 cohort indicate FDA is exceeding the MDUFMA performance goal for issuing all other first action letters.

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed[15]	Percent on Time[13]	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**	**4 / 5**	**80%**	**70%**
		2006	**N**	**0 / 0**	**n/a**	**80%**
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%**
		2006	**N**	**1 / 1**	**100%**	**80%**

[15] FY 2005 was revised to reflect updated information not available for the FY 2005 MDUFMA Performance Report.

Expedited PMAs

Performance

Second or Later Action Letters. Preliminary numbers for the FY 2005 cohort indicate FDA is exceeding the MDUFMA performance goal for issuing a "major deficiency" letter as the second or later action (see table below).

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed	Percent on Time[13]	MDUFMA Performance Goal
Issue a "major deficiency" letter as the second or later action	100 days	2003	Y	0 / 0	n/a	No Goal
		2004	N	0 / 1	0%	No Goal
		2005	**N**	**2 / 2**	**100%**	**70%**
		2006	**N**	**0 / 0**	**n/a**	**80%**

Amendments. FDA reviewed and acted on all amendments received for the FY 2003 through FY 2006 cohorts. Preliminary numbers for the FY 2005 cohort indicate FDA is exceeding the MDUFMA performance goal for acting on an amendment containing a complete response to a "major deficiency" or "not approvable" letter (see table below). Final numbers for the FY 2003 cohort indicate FDA exceeded the MDUFMA performance goal for acting on one amendment containing a complete response to an "approvable" letter. Preliminary numbers for the FY 2004 cohort indicate FDA is not meeting the MDUFMA performance goal.

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed	Percent on Time[13]	MDUFMA Performance Goal
Act on an amendment containing a complete response to a "major deficiency" or "not approvable" letter	170 days	2003	Y	2 / 2	100%	No Goal
		2004	N	5 / 8	63%	No Goal
		2005	**N**	**5 / 5**	**100%**	**70%**
		2006	**N**	**0 / 0**	**n/a**	**80%**
Act on an amendment containing a complete response to an "approvable" letter	30 days	**2003**	**Y**	**1 / 1**	**100%**	**90%**
		2004	**N**	**1 / 2**	**50%**	**90%**
		2005	**N**	**0 / 0**	**n/a**	**90%**
		2006	**N**	**0 / 0**	**n/a**	**90%**

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180-Day PMA Supplements

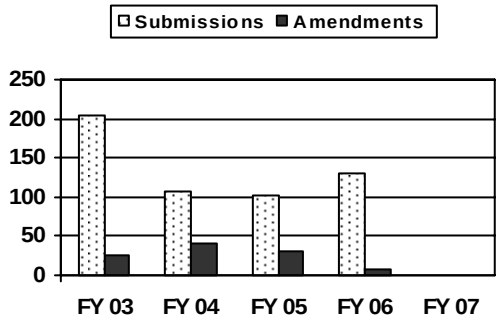
Goals

The table below summarizes the annual review time goals for 180-day PMA supplements. The 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 2006 increased compared to the FY 2004 and FY 2005 levels, but remained less than FY 2003.



180-day PMA Supplements					
Type	FY 03	FY 04	FY 05	FY 06	FY 07
Submissions[16]	**204**	**106**	**101**	**131**	--
Amendments[17]	**25**	**42**	**30**	**8**	--

[16] FY 2003 was revised to reflect updated information not available for the FY 2005 MDUFMA Performance Report.

[17] Additional amendments can still be submitted for cohorts not closed. In the FY 2005 MDUFMA Performance Report, the amendment numbers for FY 2003 through FY 2005 were 25, 38, and 6, respectively.

180-Day PMA Supplements

Performance

Decisions. FDA made decisions on all of the FY 2005 cohort and almost three-fourths (95 of 131) of the FY 2006 cohort. Final numbers for the FY 2005 cohort indicate FDA exceeded the MDUFMA performance goal for making an "FDA decision" (see table below). Preliminary numbers for the FY 2006 cohort indicate FDA is exceeding the MDUFMA performance goal.

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed[16]	Percent on Time[13]	MDUFMA Performance Goal
Make an "FDA decision"	180 days	2003	Y	192 / 204	94%	No Goal
		2004	Y	102 / 106	96%	No Goal
		2005	**Y**	**96 / 101**	**95%**	**80%**
		2006	**N**	**94 / 95**	**99%**	**80%**

First Action Letters. FDA issued first action letters for all of the FY 2005 cohort and almost three-fourths (97 of 131) of the FY 2006 cohort. Final numbers for the FY 2005 cohorts indicate FDA exceeded the MDUFMA performance goals for issuing a "not approvable" letter and for issuing all other first actions (see table below). Preliminary numbers for the FY 2006 cohorts indicate FDA is meeting or exceeding the MDUFMA performance goals.

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed[16]	Percent on Time[13]	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	**Y**	**36 / 40**	**90%**	**80%**
		2006	**N**	**22 / 26**	**85%**	**85%**
Issue all other first actions	180 days	2003	Y	164 / 172	95%	No Goal
		2004	Y	61 / 63	97%	No Goal
		2005	**Y**	**60 / 61**	**98%**	**80%**
		2006	**N**	**70 / 71**	**99%**	**85%**

180-Day PMA Supplements

Performance

Amendments. FDA reviewed and acted on all amendments received for the FY 2003 through FY 2006 cohorts. Preliminary numbers for the FY 2005 and FY 2006 cohorts indicate FDA is exceeding the MDUFMA performance goal for acting on an amendment containing a complete response to a "not approvable" letter (see table below).

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed	Percent on Time[13]	MDUFMA Performance Goal
Act on an amendment containing a complete response to a "not approvable" letter	160 days	2003	Y	24 / 25	96%	No Goal
		2004	N	41 / 42	98%	No Goal
		2005	**N**	**27 / 30**	**90%**	**80%**
		2006	**N**	**8 / 8**	**100%**	**85%**

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510(k) Premarket Notifications

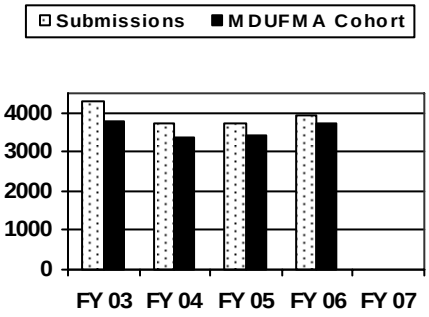
Goals

The table below summarizes the annual review time goals for 510(k) premarket notifications. The 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. 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 2006 increased compared to FY 2004 and FY 2005 levels. The MDUFMA cohort portion of 510(k) submissions increased for 3 straight years and represented over 95 percent of total submissions in FY 2006 (see graph to the right and table below).[18]



510(k) Premarket Notifications					
Type	**FY 03**	**FY 04**	**FY 05**	**FY 06**	**FY 07**
Submissions	**4,290**	**3,710**	**3,713**	**3,913**	--
MDUFMA Cohort[18]	**3,795**	**3,383**	**3,415**	**3,732**	--

[18] 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 made decisions on almost all (3,376 of 3,415) of the FY 2005 cohort and two-thirds (2,503 of 3,732) of the FY 2006 cohort. Preliminary numbers for the FY 2005 and FY 2006 cohorts indicate FDA is exceeding the MDUFMA performance goal for making a "substantially equivalent" or "not substantially equivalent" decision (see table below).

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed	Percent on Time[13]	MDUFMA Performance Goal
Make a "substantially equivalent" or "not substantially equivalent" decision	90 days	2003	Y	2,887 / 3,795	76%	No Goal
		2004	N	2,835 / 3,381	84%	No Goal
		2005	**N**	**3,090 / 3,376**	**92%**	**75%**
		2006	**N**	**2,416 / 2,503**	**97%**	**75%**

First Action Letters. FDA issued first action letters for over half (1,847 of 3,415) of the FY 2005 cohort and almost half (1,814 of 3,732) of the FY 2006 cohort. Preliminary numbers for the FY 2005 and FY 2006 cohorts indicate FDA is exceeding the MDUFMA performance goal for issuing an "additional information" letter as a first action (see table below).

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed	Percent on Time[13]	MDUFMA Performance Goal
Issue an "additional information" letter as the first action	75 days	2003	Y	1,011 / 1,726	59%	No Goal
		2004	N	1,271 / 1,618	79%	No Goal
		2005	**N**	**1,732 / 1,847**	**94%**	**70%**
		2006	**N**	**1,725 / 1,814**	**95%**	**80%**

510(k) Premarket Notifications

Performance

Second or Later Action Letters. Preliminary numbers for the FY 2005 and FY 2006 cohorts indicate FDA is exceeding the MDUFMA performance goal for issuing any second or later action letter (see table below).

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed	Percent on Time[13]	MDUFMA Performance Goal
Issue any second or later action	60 days	2003	Y	311 / 611	51%	No Goal
		2004	N	480 / 586	82%	No Goal
		2005	**N**	**611 / 667**	**92%**	**70%**
		2006	**N**	**434 / 449**	**97%**	**80%**

Biologics Licensing Applications (BLAs)

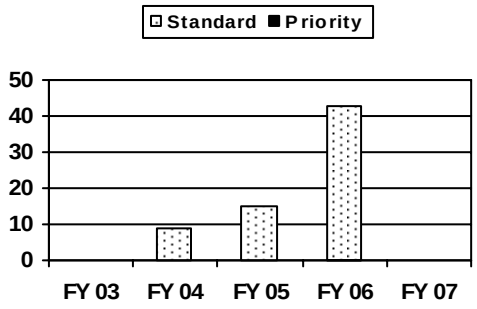
Goals

The table below summarizes two new annual review time goals for FY 2006 MDUFMA performance levels for standard and priority original BLA submissions. Performance levels increase from 75 percent in FY 2006 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 standard original BLAs (issue "complete action" letter)	10 months	No Goals			75%	90%
Review and act on priority original BLAs (issue "complete action" letter)	6 months	No Goals			75%	90%

Workload

The number of standard BLAs submitted almost tripled in FY 2006 when compared to FY 2005, reaching a 4-year high (see graph to the right and table below). No priority BLAs were received from FY 2003 through FY 2006.



Original BLAs					
Type	**FY 03**	**FY 04**	**FY 05**	**FY 06**	**FY 07**
Standard	0	9	15	43	--
Priority	0	0	0	0	--
MDUFMA Total	**0**	**9**	**15**	**43**	--

Biological Licensing Applications (BLAs)

Performance

Complete Action Letters. FDA has not completed review and action on any of the standard BLA submissions (issue "complete action" letter) received for the FY 2006 cohort (see table below). With standard BLA submissions still pending and not overdue as of September 30, 2006, it is too early to make a final performance determination for the FY 2006 cohort.

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed	Percent on Time[13]	MDUFMA Performance Goal
Review and act on standard original BLAs (issue "complete action" letter)	10 months	2003	Y	0 / 0	n/a	No Goal
		2004	Y	9 / 9	100%	No Goal
		2005	Y	15 / 15	100%	No Goal
		2006	**N**	**0 / 0**	**n/a**	**75%**
Review and act on priority original BLAs (issue "complete action" letter)	6 months	2003	Y	0 / 0	n/a	No Goal
		2004	Y	0 / 0	n/a	No Goal
		2005	Y	0 / 0	n/a	No Goal
		2006	**N**	**0 / 0**	**n/a**	**75%**

BLA Supplements

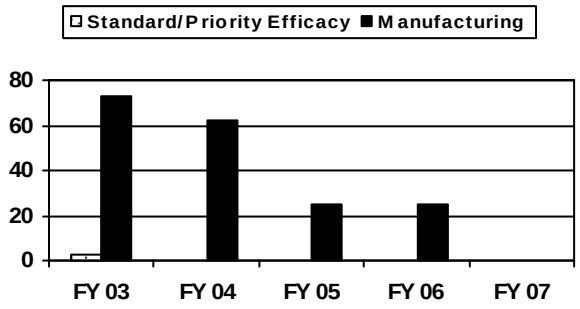
Goals

The table below summarizes three new annual review time goals for FY 2006 MDUFMA performance levels for standard and priority BLA efficacy supplements and for BLA manufacturing supplements that require prior approval. Performance levels increase from 75 percent in FY 2006 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 standard BLA efficacy supplements (issue "complete action" letter)	10 months	No Goals			75%	90%
Review and act on priority BLA efficacy supplements (issue "complete action" letter)	6 months	No Goals			75%	90%
Review and act on BLA manufacturing supplements that require prior approval (issue "complete action" letter)	4 months	No Goals			75%	90%

Workload

The total number of BLA manufacturing supplements was unchanged from FY 2005 to FY 2006 and at a lower level than FY 2003 and FY 2004 (see graph to the right and table below). The only BLA efficacy supplements received from FY 2003 through FY 2006 were three standard supplements in FY 2003.



BLA Supplements					
Type	FY 03	FY 04	FY 05	FY 06	FY 07
Standard Efficacy	3	0	0	0	--
Priority Efficacy	0	0	0	0	--
Manufacturing	73	62	25	25	--
MDUFMA Total	**76**	**62**	**25**	**25**	**--**

BLA Supplements

Performance

Complete Action Letters. FDA reviewed and acted on over four-fifths (21 of 25) of the BLA manufacturing supplements that require prior approval (issued "complete action" letters) for the FY 2006 cohort. Preliminary numbers for the FY 2006 cohort indicate FDA is exceeding the MDUFMA performance goal to review and act on BLA manufacturing supplements that require prior approval (issue "complete action" letters) (see table below). With BLA manufacturing supplement filings still pending and not overdue as of September 30, 2006, it is too early to make a final performance determination for the FY 2006 cohort.

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed	Percent on Time[13]	MDUFMA Performance Goal
Review and act on standard BLA efficacy supplements (issue "complete action" letter)	10 months	2003	Y	3 / 3	100%	No Goal
		2004	Y	0 / 0	n/a	No Goal
		2005	Y	0 / 0	n/a	No Goal
		2006	**N**	**0 / 0**	**n/a**	**75%**
Review and act on priority BLA efficacy supplements (issue "complete action" letter)	6 months	2003	Y	0 / 0	n/a	No Goal
		2004	Y	0 / 0	n/a	No Goal
		2005	Y	0 / 0	n/a	No Goal
		2006	**N**	**0 / 0**	**n/a**	**75%**
Review and act on BLA manufacturing supplements that require prior approval (issue "complete action" letter)	4 months	2003	Y	72 / 73	99%	No Goal
		2004	Y	62 / 62	100%	No Goal
		2005	Y	24 / 25	96%	No Goal
		2006	**N**	**21 / 21**	**100%**	**75%**

Resubmitted BLAs and BLA Efficacy Supplements

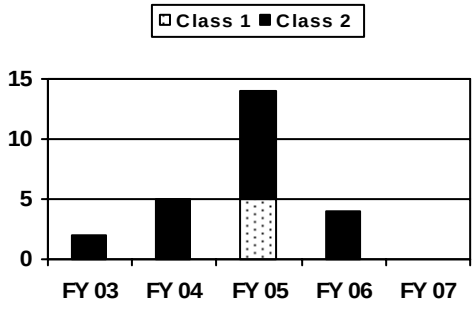
Goals

The table below summarizes the annual review time goals for resubmitted original BLAs and BLA efficacy supplements 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 number of resubmitted BLAs and BLA efficacy supplement applications returned to FY 2004 levels for both "Class 1" and "Class 2" resubmissions (see graph to the right and table below). The workload for FY 2006 was similar to the FY 2003 and FY 2004 levels.



Resubmitted BLAs and BLA Efficacy Supplements					
Type	FY 03	FY 04	FY 05	FY 06	FY 07
"Class 1"	0	0	5	0	--
"Class 2"	2	5	9	4	--
MDUFMA Total	**2**	**5**	**14**	**4**	--

Resubmitted BLAs and BLA Efficacy Supplements

Performance

Resubmissions. FDA reviewed and acted on all of the resubmitted "Class 1" and "Class 2" BLAs and BLA efficacy supplements for the FY 2005 cohorts and all but one (3 of 4) for the FY 2006 cohorts. Final numbers for the FY 2005 cohorts indicate FDA exceeded the MDUFMA performance goals for the "Class 1" and "Class 2" resubmissions (see table below). Preliminary numbers for the FY 2006 cohort indicate FDA is exceeding the MDUFMA performance goal for the "Class 2" resubmissions. With one "Class 2" resubmission still pending and not overdue as of September 30, 2006, it is too early to make a final performance determination for the FY 2006 cohort.

Goals	Review Within	Fiscal Year	Cohort Closed	Number on Time / Actions Completed	Percent on Time[13]	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%**
		2006	**N**	**0 / 0**	**n/a**	**80%**
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	**Y**	**9 / 9**	**100%**	**75%**
		2006	**N**	**3 / 3**	**100%**	**80%**

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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

FDA's FY 2006 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	FY 06
HDEs - Filing to first action (average FDA days)	53	48	52	63	67
HDEs - Elapsed time to approval (average FDA days)	175	152	182	223	297
IDEs - FDA review time (average FDA days)	28	27	28	28	28
IDEs - Percent of decisions made within 30 days	99%	100%	100%	96%	99%
IDE Amendments - FDA review time (average FDA days)	18	19	18	20	19
IDE Amendments - Percent of decisions made within 30 days	100%	100%	100%	98%	100%
IDE Supplements - FDA review time (average FDA days)	20	19	19	19	20
IDE Supplements - Percent of decisions made within 30 days	100%	100%	100%	100%	100%
CBER Performance Indicators	**FY 02**	**FY 03**	**FY 04**	**FY 05**	**FY 06**
BLA Supplements (CBE/CBE-30) - Percent reviewed and acted on within 6 months	99%	97%	100%	100%	100%
PMA Supplements (CBE) - Percent of decisions made within 180 days	100%	100%	100%	100%	100%
PMA Supplements (135-day) - Percent of decisions made within 135 days	NR	100%	100%	100%	100%
PMA Supplements (CBE-30) - Percent of decisions made within 30 days	67%	100%	100%	100%	100%

KEY: HDEs-Humanitarian Device Exemptions; IDEs-Investigational Device Exemptions; BLA-Biologics Licensing 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 with regulated industry 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 2006, FDA participated in more than 1,500 premarket meetings with industry. The more formal types of meetings (agreement, determination, and 100-day meetings) are not used as frequently by premarket applicants.

Resources Applied to MDUFMA Activities

FDA's annual financial Reports to Congress provide information on FDA's use of resources for the MDUFMA program and are available at: http://www.fda.gov/oc/mdufma.

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, available at: http://www.fda.gov/cdrh/mdufma/guidance/1201.html. 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*, available at: http://www.fda.gov/cdrh/mdufma/guidance/835.html. 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.

Although FDA extended the modular review program to panel-track PMA supplements, as of the close of FY 2006, FDA has not received a modular panel-track PMA supplement.

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*, available at: http://www.fda.gov/cdrh/mdufma/guidance/1201.html. 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*, available at: http://www.fda.gov/cdrh/mdufma/guidance/1215.html. 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, available at: http://www.fda.gov/cber/gdlns/eind.pdf. 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, 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. In FY 2006, industry submitted 85 Turbo 510(k) electronic submissions. CDRH also developed 24 electronic templates for radiation safety reports required of electronic product manufacturers. To date, 448 radiological health stakeholders downloaded the CeSub software and 176 electronic radiation safety reports have been submitted by the electronic product industry. In FY 2006, CDRH also initiated 100 percent scanning of paper radiation safety reports, which are loaded into the Image 2000 system for electronic review.

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. In FY 2006, FDA issued guidance that: 1) helps industry better understand the preapproval inspection process, so they will be better prepared for their inspections; and 2) explains how the Centers will work with applicants, the Office of Regulatory Affairs (ORA), and with ORA field inspectors to improve the timeliness of preapproval inspections.

Next Steps to Implement MDUFMA Successfully

FDA faces a number of critical implementation steps in meeting MDUFMA performance goals that 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 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 preapproval inspections, both within the United States and abroad.

- 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.

FDA will work with stakeholders and Congress to secure timely reauthorization of MDUFMA. Reauthorization is essential if FDA is to preserve and build upon the improvements to FDA's device review performance that are being achieved under MDUFMA.

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Appendix A: November 14, 2002, Commitment Letter from HHS Secretary 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.[19]

(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.

[19] 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 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 FDA's progress, quantitative measures are used. 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 (for example, expedited PMAs),
- a clear definition of the action FDA is to take (for example, issue a first action major deficiency letter),
- an objective review time standard (that is, the number of days or months within which FDA is expected to take action),
- a quantifiable measure of performance (that is, 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 (that is, the fiscal year for which FDA performance will be evaluated).

MDUFMA's review performance goal progress is measured using quantitative methods.[20] 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.

[20] 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 measures cannot be used to evaluate FDA's progress in implementing a performance goal, FDA uses descriptive measures to assess its performance. FDA reports its progress in narrative accounts that outline the specific actions FDA has taken; the results are attributed to those actions.

MDUFMA commitments use descriptive measures to assess performance.[21] 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.

[21] 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 goals. Submissions received since the start of FY 2003 (October 1, 2002) are subject to MDUFMA performance goals, and will be reflected in FDA's performance statistics.

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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 (approval, approvable, approvable pending GMP inspection, not approvable, denial)	180 days	—	—	—	—	50%
• 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%

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%
• 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 Licensing 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] Results are as of September 30, 2006, and are subject to revision over time as FDA completes additional actions within each cohort.

[2] 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.

[3] HHS Secretary 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.

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

[5] FDA and industry agree that, for FY 2007, FDA will manage its resources towards meeting the 180-day decision goal rather than the 150-day cycle goal for PMAs. FDA and industry understand that this focus on the 180-day decision goal may mean that FDA does not meet the 150-day cycle goal.

[6] 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.

[7] 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.

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

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

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

[11] FDA did not receive any Premarket Reports in FY 2003 through FY 2006.

[12] Additional amendments can still be submitted for cohorts not closed. In the FY 2005 MDUFMA Performance Report, the amendment numbers for FY 2003 through FY 2005 were 27, 27, and 3, respectively.

[13] Final performance cannot be determined until cohort activity is completed.

[14] Additional amendments can still be submitted for cohorts not closed. In the FY 2005 MDUFMA Performance Report, the amendment numbers for FY 2003 through FY 2005 were 3, 9, and 1, respectively.

[15] FY 2005 was revised to reflect updated information not available for the FY 2005 MDUFMA Performance Report.

[16] FY 2003 was revised to reflect updated information not available for the FY 2005 MDUFMA Performance Report.

[17] Additional amendments can still be submitted for cohorts not closed. In the FY 2005 MDUFMA Performance Report, the amendment numbers for FY 2003 through FY 2005 were 25, 38, and 6, respectively.

[18] 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.

[19] 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.

[20] 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).

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

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

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