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Report to Congressional Committees

September 2005

FOOD AND DRUG ADMINISTRATION

Limited Available Data Indicate That FDA Has Been Meeting Some Goals for Review of Medical Device Applications

GAO-05-1042

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Highlights

Highlights of GAO-05-1042, a report to congressional committees

Why GAO Did This Study

The Food and Drug Administration (FDA) reviews applications from manufacturers that wish to market medical devices in the United States. To facilitate prompt approval of new devices and clearance of devices that are substantially equivalent to those legally on the market, the Congress passed the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). The act authorizes FDA to collect user fees from manufacturers and, in return, requires FDA to meet performance goals tied to the agency's review process. These goals are linked to certain actions FDA may take during the application review process. The goals specify lengths of time for taking these actions and the percentage of actions the agency is to take within specified time frames.

MDUFMA requires GAO to report on whether FDA is meeting performance goals established by the Secretary of Health and Human Services for fiscal year 2005 and whether FDA is likely to meet the goals established for fiscal year 2006.

GAO analyzed data provided by FDA that are based on actions taken on applications FDA received from October 1, 2002, through March 31, 2005. GAO used FDA's performance on applications received in fiscal years 2003 and 2004 as an indicator of the agency's likely performance.

www.gao.gov/cgi-bin/getrpt?GAO-05-1042.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse at (202) 512-7119 or crossem@gao.gov.

What GAO Found

Limited available data indicate that FDA has been meeting some MDUFMA performance goals established for fiscal year 2005. It is uncertain, however, whether FDA will meet all of the goals. FDA met most of the MDUFMA 2005 performance goals for which data were sufficiently complete to measure the agency's performance. As of March 31, 2005, FDA had sufficiently complete data from applications received in fiscal year 2003 to measure performance against 11 of the 20 goals established for fiscal year 2005. FDA met 9 of those 11 goals. For applications received in fiscal year 2004, FDA had sufficiently complete data to measure performance against 10 goals and met 9 of them. When FDA did not have sufficiently complete data to evaluate performance, GAO reviewed preliminary data from applications received in fiscal years 2003, 2004, and 2005. These data suggest that FDA has taken actions tied to many of the fiscal year 2005 goals within specified time frames. These data are preliminary because some applications from each year were pending within the review process and FDA could receive and act on additional applications or amendments to applications. For example, as of March 31, 2005, about half of the applications FDA had received in fiscal year 2005 were pending action by FDA or responses from manufacturers. Because FDA's performance against the MDUFMA performance goals is based on the percentages of actions the agency takes on applications within required time frames, FDA's performance results could change as the agency completes actions on all applications and amendments for which the performance goals apply.

The limited data available on FDA's performance suggest that FDA is likely to meet some fiscal year 2006 performance goals. GAO's analysis of FDA's past performance shows that FDA met most of the MDUFMA 2006 performance goals for which it had sufficiently complete data to evaluate its performance. As of March 31, 2005, FDA has sufficiently complete data from applications received in fiscal year 2003 to measure performance against 14 of 26 goals established for fiscal year 2006. FDA met 12 of those 14 goals. FDA also had sufficiently complete data from applications received in fiscal year 2004 to measure performance against 12 performance goals and met 9 of those 12 goals. GAO also reviewed preliminary data from applications FDA received in fiscal years 2003, 2004, and 2005 and found that FDA took actions tied to many of the fiscal year 2006 goals within specified time frames. Most of these results are preliminary, however, and FDA's performance could change as the agency completes actions for applications received in fiscal years 2003, 2004, and 2005 and receives applications in fiscal year 2006.

FDA concurred with GAO's findings.

Contents

Abbreviations

BLA	biologics license application
CBER	Center for Biologics Evaluation and Research
CDRH	Center for Devices and Radiological Health
FDA	Food and Drug Administration
GMP	good manufacturing practices
MDUFMA	Medical Device User Fee and Modernization Act of 2002
PMA	premarket approval

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United States Government Accountability Office
Washington, DC 20548

September 30, 2005

The Honorable Mike Enzi
Chairman
The Honorable Edward M. Kennedy
Ranking Minority Member
Committee on Health, Education, Labor and Pensions
United States Senate

The Honorable Joe Barton
Chairman
The Honorable John D. Dingell
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives

The Food and Drug Administration (FDA) is responsible for regulating medical devices—such as tongue depressors, pacemakers, and artificial hearts—to provide reasonable assurance that they are safe and effective for human use. As part of its regulatory responsibilities, FDA reviews applications from manufacturers that wish to market their medical devices in the United States, including new devices and devices that may be substantially equivalent to those already on the market. When required, FDA also inspects manufacturers' establishments prior to making a decision. Each year FDA receives approximately 10,000 medical device applications. Members of the Congress, representatives of the medical device industry, and others have expressed concern that the length of time it takes FDA to review applications for marketing medical devices could delay patients' access to useful, and possibly life-saving, medical devices.

In October 2002, the Congress passed the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) to provide FDA with additional resources to ensure prompt approval or clearance[1] of applications for marketing medical devices and licensing biological products.[2] MDUFMA

[1]The term approval is generally used for applications for new devices, while the term clearance is used for devices that are substantially equivalent to those legally on the market.

[2]Pub. L. No. 107-250, sec. 102(a), §§ 737 and 738, 116 Stat. 1588 (to be codified as amended at 21 U.S.C. §§ 379i and 379j).

authorized FDA to collect user fees from manufacturers that submit several types of applications to FDA for marketing medical devices. In return, MDUFMA requires FDA to meet performance goals tied to the review of certain medical device and biological license applications, at least to the extent practicable. MDUFMA also required the Secretary of Health and Human Services to develop the specific goals FDA must meet. The Secretary developed performance goals for fiscal years 2003 through 2007. To help FDA meet the MDUFMA performance goals, the Secretary also identified several goal-related activities for FDA to undertake, such as hiring additional review staff.

MDUFMA performance goals are linked to certain actions FDA may take during the application review process and specify lengths of time for taking these actions. Data to measure FDA's performance against the MDUFMA performance goals are based on the percentages of actions the agency takes on applications within specified time frames. For example, one of the performance goals is linked to the time it takes FDA to review and make a decision about certain applications to market devices that may be substantially equivalent to devices that are already on the market. To meet the performance goal established for fiscal year 2005, FDA must reach a decision about substantial equivalence within 90 days for 75 percent of such applications received in the fiscal year. In general, the time frames established by MDUFMA performance goals do not hold FDA accountable for the time it takes manufacturers to respond to the agency if the agency determines that substantial additional information is needed before a decision can be reached.

The number of MDUFMA performance goals that FDA must meet increases over time, and the percentage of actions taken within the specified time frame for some goals also increases over time. For fiscal years 2003 and 2004, FDA was to meet the same 2 performance goals for each year. For fiscal year 2005, FDA was to meet those 2 goals and an additional 18 performance goals, for a total of 20. For fiscal year 2006, FDA is to meet these 20 goals and an additional 6 performance goals, for a total of 26. The goals established for fiscal year 2006 are tied to more types of applications than the goals established for fiscal year 2005. In addition, 16 of the performance goals established for fiscal year 2006 require that review actions be taken within the specified time frames on a higher percentage of applications—for example, on 80 percent rather than 75 percent of the applications—than was required for similar goals established for fiscal year 2005.

MDUFMA requires us to report on FDA's performance as measured against these performance goals. Our first report, issued in August, 2004,[3] indicated that FDA had limited data that could be used to measure the agency's performance. As a result, it was uncertain whether FDA would meet the MDUFMA performance goals for fiscal years 2003, 2004, or 2005. As we reported, FDA's performance data were preliminary, in part because many of the applications received in fiscal year 2003 and the first 6 months of fiscal year 2004 were pending within the review process, that is, awaiting action by FDA or responses from manufacturers. Because FDA measures its progress in meeting the MDUFMA performance goals by the percentage of actions the agency takes within specified time frames, we noted that performance results could change as FDA completes its actions on these applications.

This report responds to the MDUFMA requirement that we report on whether FDA is meeting the MDUFMA performance goals established for fiscal year 2005 and whether FDA is likely to meet the goals established for fiscal year 2006.[4] To assess FDA's performance against the 20 MDUFMA performance goals that were established for fiscal year 2005, we analyzed performance data from applications the agency received during the first 6 months of fiscal year 2005. To supplement the data from the first 6 months of fiscal year 2005, we also compared FDA's actions on applications received in fiscal years 2003 and 2004 against the 20 MDUFMA performance goals established for fiscal year 2005, a comparison FDA also conducts. We used FDA's performance on applications received in fiscal years 2003 and 2004 as an indicator of the agency's experience in meeting the fiscal year 2005 goals and therefore its likely performance in fiscal year 2005. Similarly, to determine the likelihood of FDA meeting its fiscal year 2006 MDUFMA performance goals, we compared performance data from applications the agency received in fiscal years 2003 and 2004 and the first 6 months of fiscal year 2005 with the 26 MDUFMA performance goals that will be effective in fiscal year 2006. In other words, we analyzed performance data collected by FDA for actions taken on all applications that were tied to performance goals established for fiscal years 2005 or 2006 that the agency received from fiscal year 2003 through the first 6 months of fiscal year 2005 (Oct. 1, 2004, through Mar. 31, 2005).

[3]See GAO, *Food and Drug Administration: Data to Measure the Timeliness of Reviews of Medical Device Applications Are Limited*, GAO-04-1022 (Washington, D.C.: Aug. 30, 2004).

[4]21 U.S.C. § 379j(g)(1)(B)(i)(II) (2000).

In conducting our work, we made a distinction between data that were sufficiently complete to evaluate FDA's performance and preliminary data that were not sufficiently complete for that purpose. FDA's data for some MDUFMA performance goals were not complete because applications were pending within the review process or because manufacturers can submit additional applications or amendments to their applications. We defined the data as sufficiently complete to evaluate performance when we could determine whether FDA would or would not meet the performance goal. For example, FDA had data on eight of nine applications tied to one performance goal and took action within the specified time frame for each of those eight applications. These data were sufficiently complete to evaluate FDA's performance because the action was taken within the specified time frame for at least 75 percent of applications—the percentage established for this performance goal. In contrast, when FDA's data were not sufficiently complete to evaluate performance, we considered data on FDA's performance to be preliminary.

To conduct our work and to determine what steps FDA has taken to help meet its MDUFMA goals, we also reviewed our previous work on FDA's performance as measured by MDUFMA performance goals, reviewed relevant documents, and interviewed officials from FDA's Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER). In addition, we reviewed FDA's procedures for verifying the accuracy and consistency of reported performance data. We determined that the performance data were sufficiently reliable for the purposes of this report. We conducted our work from May 2005 through September 2005 in accordance with generally accepted government auditing standards.

Results in Brief

The available sufficiently complete data indicate that FDA has been meeting some MDUFMA performance goals established for fiscal year 2005. It is uncertain, however, whether FDA will meet all of the goals. Our analysis shows that FDA met most of the MDUFMA 2005 performance goals for which there were sufficiently complete data to measure the agency's performance. These data involve actions taken through March 31, 2005, on applications that FDA received in fiscal years 2003 and 2004 and were used to measure the agency's performance against about half of the performance goals established for fiscal year 2005. As of March 31, 2005, FDA had sufficiently complete data from applications received in fiscal year 2003 to measure performance against 11 of the 20 goals established for fiscal year 2005. FDA met 9 of those 11 goals. For applications received

in fiscal year 2004, FDA had sufficiently complete data to measure performance against 10 goals and met 9 of them. When FDA did not have sufficiently complete data to evaluate performance against a MDUFMA performance goal, we reviewed preliminary data from applications received in fiscal years 2003, 2004, and 2005. These data suggest that FDA has taken actions tied to most of the remaining fiscal year 2005 goals within the specified time frames. For example, FDA had preliminary data from applications received in the first 6 months of fiscal year 2005 on 11 goals and took actions tied to these goals within the specified time frames. Because FDA's performance against the MDUFMA performance goals is based on the percentages of actions the agency takes on applications within required time frames, FDA's performance results could change as the agency completes additional actions on applications that are pending within the review process or as manufacturers submit additional applications or amendments to applications.

The limited data available on FDA's performance suggest that FDA is likely to meet some of the fiscal year 2006 performance goals. Our analysis of FDA's past performance shows that FDA has been meeting most of the MDUFMA 2006 performance goals for which it had sufficiently complete data. As of March 31, 2005, FDA had sufficiently complete data from applications received in fiscal year 2003 to measure performance against 14 of 26 goals established for fiscal year 2006. FDA met 12 of those 14 goals. FDA also had sufficiently complete data from applications received in fiscal year 2004 to measure performance against 12 performance goals and met 9 of those 12 goals. We also reviewed preliminary data about those goals for which FDA did not have sufficiently complete data to evaluate performance. FDA's preliminary data from applications received in fiscal years 2003 and 2004 and the first 6 months of fiscal year 2005 showed that FDA took actions tied to most of the remaining fiscal year 2006 goals within specified time frames. For example, FDA had preliminary data from applications received in fiscal year 2005 for 13 of the 26 goals. FDA took actions tied to these 13 goals within the established time frames. These results are preliminary, however, and could change as FDA completes actions tied to fiscal year 2006 goals for applications received in fiscal years 2003, 2004, and 2005. FDA's performance could also change when FDA starts receiving applications in fiscal year 2006.

FDA concurred with our findings.

Background

Under the Federal Food, Drug, and Cosmetic Act,[5] FDA is responsible for ensuring that medical devices are reasonably safe and effective before they go to market (premarket) and that marketed device products remain safe (postmarket). Two FDA centers, CDRH and CBER, are responsible for reviewing applications to market medical devices.[6] CDRH reviews applications for the majority of these devices, such as artificial hearts, dialysis machines, and radiological devices. CBER reviews applications for devices used in the testing and manufacture of biological products, including diagnostic tests intended to screen blood donors (such as for the human immunodeficiency virus), as well as therapeutic devices used in cell and gene therapies. FDA also inspects manufacturers' establishments to assess compliance with good manufacturing practices (GMP). During these inspections, FDA investigators examine manufacturing facilities, records of manufacturing processes, and corrective action programs.

Types of Applications Reviewed under MDUFMA Performance Goals

Nine types of applications for medical devices and biological products are subject to the MDUFMA performance goals established by the Secretary of Health and Human Services for fiscal years 2005 or 2006:[7]

- Original Premarket Approval (PMA) applications are generally required when the device is new or when the risks associated with the device are considerable (as would be the case if the device is to be implanted in the body for life-supporting purposes).
- Expedited PMAs are used when FDA has granted priority status to an application to market a medical device because it is intended to treat or diagnose a life-threatening or irreversibly debilitating disease or condition and to address an unmet medical need.
- Premarket Reports are applications 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.

[5]Ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301 et seq. (2000)).

[6]In general, an application to market a medical device includes information on the device and its components; proposed labeling for the device; and when applicable, clinical and nonclinical studies that provide reasonable assurance of the device's safety and effectiveness.

[7]Some types of applications that involve biologics licenses are linked to MDUFMA performance goals established for 2006, but not for 2005.

- Premarket Notifications, or 510(k)s,[8] are applications used when the intent is to market a type of device that may be substantially equivalent[9] to a legally marketed device that was not subject to premarket approval.
- Panel-Track Supplements are applications used to supplement approved PMAs or Premarket Reports. These supplements typically request approval of a significant change in the design or performance of a device, or for a new purpose for using a device.
- 180-Day PMA Supplements are also used to supplement approved PMAs or Premarket Reports. These supplements typically request 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.
- Biologics license applications (BLA) request permission to introduce and license biological products into interstate commerce. There are two types of BLAs that are tied to MDUFMA performance goals. Priority BLAs are for products 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. Nonpriority BLAs are considered standard BLAs.
- BLA Supplements are used to supplement approved BLAs by 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. There are MDUFMA performance goals linked to three types of BLA supplements—BLA manufacturing supplements that require prior approval and two types of BLA efficacy supplements. Manufacturing supplements that require prior approval address proposed changes in the manufacture of the biologic and generally do not require submission of substantive clinical data. Efficacy supplements include both standard and priority efficacy supplements and require submission of substantive clinical data.
- BLA Resubmissions and BLA Efficacy Supplement Resubmissions are used to respond to a letter from FDA indicating that the information included in a BLA or BLA Efficacy Supplement was deficient. FDA classifies these resubmissions into two groups according to the type of

[8]FDA refers to a premarket notification submission as a 510(k) because the requirement for them is set out in section 510(k) of the Federal Food, Drug, and Cosmetic Act. 42 U.S.C. § 360(k) (2000).

[9]Substantial equivalence means that a device has (1) the same intended use and same technological characteristics as a marketed device or (2) the same intended use and different technological characteristics, but is as safe and effective as the marketed device and does not raise new questions of safety and effectiveness.

information they provide. 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.

FDA's Medical Device Application Review Processes

Each of the 2005 and 2006 MDUFMA performance goals are linked to actions FDA takes under one of three processes for reviewing medical device applications: the PMA review process, the 510(k) review process, and the BLA review process.

The PMA Review Process

Under the PMA review process, FDA reviews applications for new devices or those for which risks associated with the device are considerable. Applications reviewed under this process include Original PMAs, Expedited PMAs, Premarket Reports, Panel-Track Supplements, and 180-Day PMA Supplements. After an initial screening of an application and determination that the review should proceed,[10] FDA multidisciplinary staff conduct a scientific review of the application.[11] (See fig. 1.) If FDA determines that it needs significant additional information to complete its scientific review, FDA issues a "major deficiency letter" to the manufacturer identifying the information that is required. The manufacturer can respond to FDA's request by submitting an amendment to the original application. FDA then proceeds with its review of the amended application. FDA can issue additional major deficiency letters and review additional amendments until FDA determines that it has sufficient information to make a decision. As part of its review, FDA may refer applications to an external advisory committee for evaluation. FDA takes this step when a device is the first of its kind or when the agency believes it would be useful to have independent expertise and technical assistance to properly evaluate the safety and effectiveness of the device.[12] For applications referred to an advisory committee, the committee provides input to FDA on the safety and effectiveness of the devices.

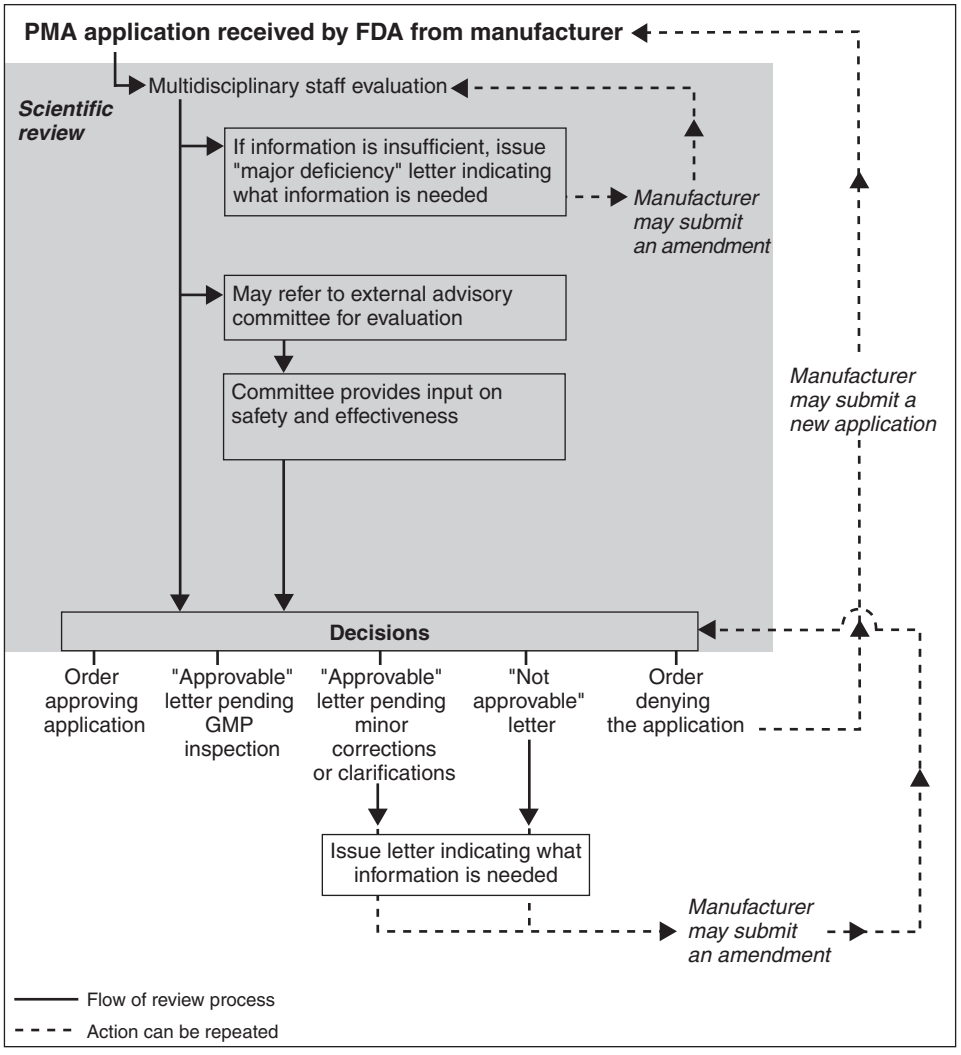
[10]This initial screening is called a filing review.

[11]The scientific review can include reviews of results from clinical investigations of the device that involve human subjects. FDA also reviews nonclinical studies of the device, and studies that may include microbiological, toxicological, and engineering tests.

[12]For example, approximately 22 percent of PMAs and Expedited PMAs were referred to external advisory committees in fiscal years 2002 and 2003. The percentage in fiscal year 2004 was closer to 40 percent. FDA does not refer 180-Day PMA Supplements to external advisory committees.

Taking the committee's input into consideration, FDA then makes a decision.

Figure 1: PMA Review Process



Source: GAO.

Note: This flow chart presents the typical review process for applications for which FDA has conducted an initial screening and determined that the review should proceed.

FDA may make one of five decisions. FDA may (1) issue an order approving the application, which allows the manufacturer to begin

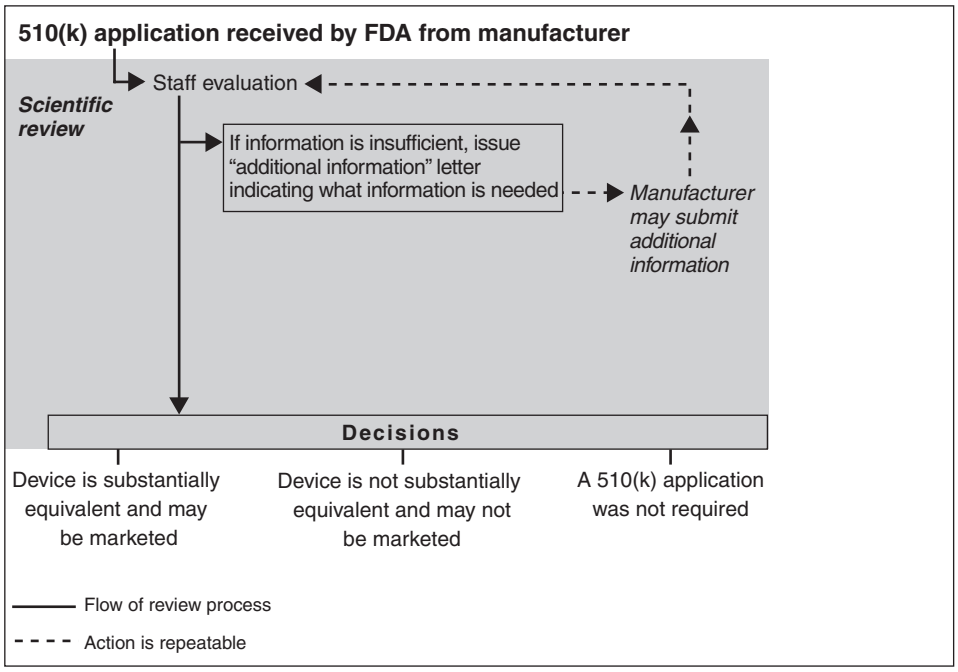
marketing the device; (2) send the manufacturer an "approvable" letter pending a GMP inspection, which indicates that FDA should be able to approve the device after the agency determines that the manufacturer's device establishment is in compliance with GMP requirements; (3) send the manufacturer an approvable letter indicating that the agency should be able to approve the device if the manufacturer can make minor corrections or clarifications to the application; (4) issue a "not approvable" letter informing the manufacturer that FDA does not believe that the application can be approved because the data provided by the manufacturer do not demonstrate that the device is reasonably safe and effective; or (5) issue an order denying approval of the application, which informs the manufacturer that the agency has completed its scientific review, identified major safety or effectiveness problems, and decided not to approve the application.

Two of these possible decisions result in issuance of letters indicating that an application has informational deficiencies—approvable letters requesting minor corrections or clarifications and not approvable letters. The manufacturer can respond to these letters by submitting an amendment to the original application. FDA then reviews the amendment. FDA can issue additional letters indicating that information is deficient and review additional amendments until FDA determines that it has sufficient information to determine whether to approve or deny the application. For example, if FDA determines that a manufacturer's amendment to an approvable letter requesting minor corrections or clarifications does not address all of FDA's questions, then FDA can issue another approvable letter pending minor corrections or clarifications or a not approvable letter.

The 510(k) Review Process

Under the 510(k) review process, FDA reviews applications to market a device that may be substantially equivalent to a legally marketed device that was not subject to premarket approval (see fig. 2). FDA staff conduct a scientific review of the application. When a 510(k) application lacks information necessary for FDA to reach a decision, the agency may issue an "additional information" letter that indicates that the information is insufficient. The manufacturer may then submit additional information. Once FDA has obtained sufficient information from the manufacturer, FDA may make one of three decisions: FDA may decide that (1) the device is substantially equivalent and therefore may be marketed, (2) the device is not substantially equivalent and may not be marketed, or (3) a 510(k) application was not required because the product is not regulated as a device or the device is exempt from the requirements for premarket notification.

Figure 2: 510(k) Review Process



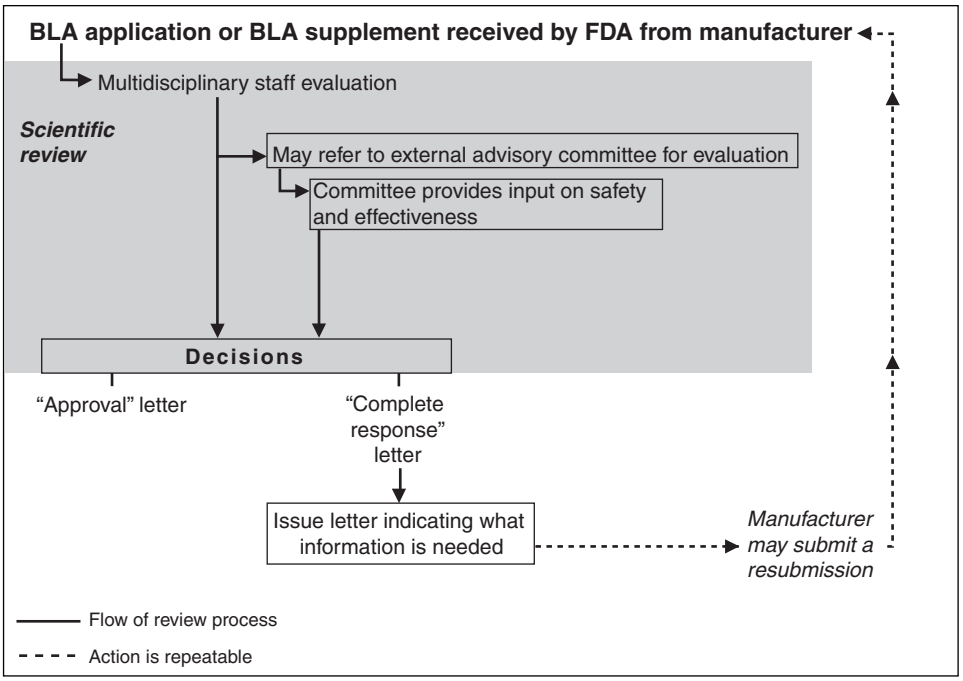
Source: GAO.

Note: This flow chart presents the typical review process to determine whether a 510(k) application is required and, if so, whether a device is substantially equivalent to a legally marketed device that was not subject to premarket approval.

The BLA Review Process

Under the BLA review process, FDA determines whether to approve licenses for biological products (see fig. 3). Applications reviewed under this process include BLAs, BLA Supplements, BLA Resubmissions, and BLA Supplement Resubmissions. After an initial screening of an application and determination that the review should proceed, staff conduct a multidisciplinary scientific review of the application. As part of its review, FDA may refer applications to an external advisory committee. After reviewing the application and taking into consideration any input from an external advisory committee, FDA may make one of two decisions. FDA may issue (1) an approval letter or (2) a "complete response" letter, which informs the manufacturer of deficiencies in the information provided in the application. The manufacturer can provide the information specified in a "complete response" letter in a BLA Resubmission or BLA Supplement Resubmission.

Figure 3: BLA Review Process



Source: GAO.

Note: This flow chart presents the typical review process for BLA-related applications for which FDA has conducted an initial screening and determined that the review should proceed.

Measuring FDA's Performance under MDUFMA

The MDUFMA performance goals specify a length of time for taking an action during the review process, which can include making a decision. The goals designate a certain percentage of these actions that must occur within the specified period for FDA to meet the performance goals. To assess its performance against the MDUFMA performance goals, FDA measures the time the agency takes to complete certain actions and make

decisions—but not the time it takes a manufacturer to respond to a letter from FDA.[13]

The data for measuring FDA's performance against a specific fiscal year's MDUFMA performance goals are based on all the applications the agency received in that year, known as a cohort,[14] and are not complete until all applicable actions have been taken. As a result, data are preliminary until FDA has completed all actions tied to the goal for all applications in a cohort—a process that, for PMAs, can take up to 3 or 4 years. For example, one performance goal established for fiscal year 2005 is tied to amendments to PMAs that are submitted in response to major deficiency or not approvable letters. Data on FDA's performance on this goal will not be complete until after FDA has issued all major deficiency and not approvable letters it decides to issue for applications received in fiscal year 2005 and then either (1) received, reviewed, and acted on all amendments submitted in response or (2) determined that manufacturers have withdrawn their applications.

For fiscal year 2005, FDA is to meet 20 performance goals and for fiscal year 2006 FDA is to meet an additional 6 performance goals, for a total of 26. (See table 1.) The percentage of applications for which the action must be taken within the specified time frame is higher in fiscal year 2006 than in fiscal year 2005 for 16 of the performance goals that are applicable for both years.

[13]If a manufacturer submits an amendment that contains substantial new information while FDA is reviewing a PMA, Expedited PMA, Premarket Report, Panel-Track Supplement, or 180-Day PMA Supplement without having received a request for additional information from FDA, the time period allowed for the review is extended. There are limits on the length of time manufacturers have to respond to certain letters indicating that FDA needs additional information to reach a decision about a device. For example, as required by FDA regulation, manufacturers who have submitted PMAs have 180 days to submit amendments in response to major deficiency letters. Manufacturers submitting amendments to PMAs can also apply for extensions of up to 180 days beyond the required response time. Manufacturers who have submitted 510(k)s have 30 days to respond to first or subsequent letters requesting additional information and can apply for extensions of up to 180 days from the date of the first or subsequent letters.

[14]FDA refers to cohorts as "receipt cohorts."

Table 1: MDUFMA Performance Goals for Fiscal Years 2005 and 2006

Type of application	FDA actions, including decisions	Performance goal		
		Review time	Percentage of actions taken on applications received in fiscal year 2005 cohort required to meet review time	Percentage of actions taken on applications received in fiscal year 2006 cohort required to meet review time
PMAs, Panel-Track Supplements, and Premarket Reports[a]	Issue a decision letter[b]	320 days	Not applicable	80
	Issue a first major deficiency letter	150 days	75	80
	Issue a decision letter as a first action on an application[b]	180 days	75	80
	Issue a second or subsequent major deficiency letter	120 days	75	80
	Act on an amendment containing a complete response to a major deficiency or not approvable letter	180 days	75	80
	Act on an amendment containing a complete response to an approvable letter pending minor corrections or clarifications	30 days	90	90
Expedited PMAs	Issue a decision letter[b]	300 days	70	80
	Issue a first major deficiency letter	120 days	70	80
	Issue a decision letter as a first action on an application[b]	170 days	70	80
	Issue a second or subsequent major deficiency letter	100 days	70	80
	Act on an amendment containing a complete response to a major deficiency or not approvable letter	170 days	70	80
	Act on an amendment containing a complete response to an approvable letter pending minor corrections or clarifications	30 days	90	90
180-Day PMA Supplements	Issue a decision letter[b]	180 days	80	80
	Issue a not approvable letter as a first action on an application	120 days	80	85
	Issue a decision letter other than a not approvable letter as a first action on an application[b]	180 days	80	85
	Act on an amendment containing a complete response to a not approvable letter	160 days	80	85

Type of application	FDA actions, including decisions	Performance goal		
		Review time	Percentage of actions taken on applications received in fiscal year 2005 cohort required to meet review time	Percentage of actions taken on applications received in fiscal year 2006 cohort required to meet review time
510(k)s	Issue a decision letter[c]	90 days	75	75
	Issue a first additional information letter	75 days	70	80
	Issue a second or subsequent additional information letter	60 days	70	80
BLAs	Review and act on a standard original BLA	10 months	Not applicable	75
	Review and act on a priority original BLA	6 months	Not applicable	75
BLA Supplements	Review and act on a standard BLA efficacy supplement	10 months	Not applicable	75
	Review and act on a priority BLA efficacy supplement	6 months	Not applicable	75
	Review and act on a BLA manufacturing supplement that requires prior approval	4 months	Not applicable	75
BLA Resubmissions and BLA Efficacy Supplement Resubmissions	Review and act on a Class 1 resubmission to an original BLA or BLA efficacy supplement	2 months	75	80
	Review and act on a Class 2 resubmission to an original BLA or BLA efficacy supplement	6 months	75	80

Source: GAO analysis of FDA data.

[a]FDA groups these types of applications when measuring performance for this goal.

[b]A decision letter for a PMA, Panel-Track Supplement, Premarket Report, Expedited PMA, or 180-Day PMA Supplement can indicate approval, approvable pending GMP inspection, approvable pending minor corrections or clarifications, not approvable, or denial. MDUFMA performance goals linked to issuance of a decision letter for these applications include a performance goal that is linked to issuance of a decision letter as a first action on an application and a performance goal that is linked to issuance of a decision letter regardless of whether that letter is issued as a first or later action.

[c]A decision letter for a 510(k) can indicate that the device may be marketed because it is substantially equivalent to one already on the market or may not be marketed because it is not substantially equivalent.

Limited Available Data Indicate That FDA Has Been Meeting Some Performance Goals Established for Fiscal Year 2005

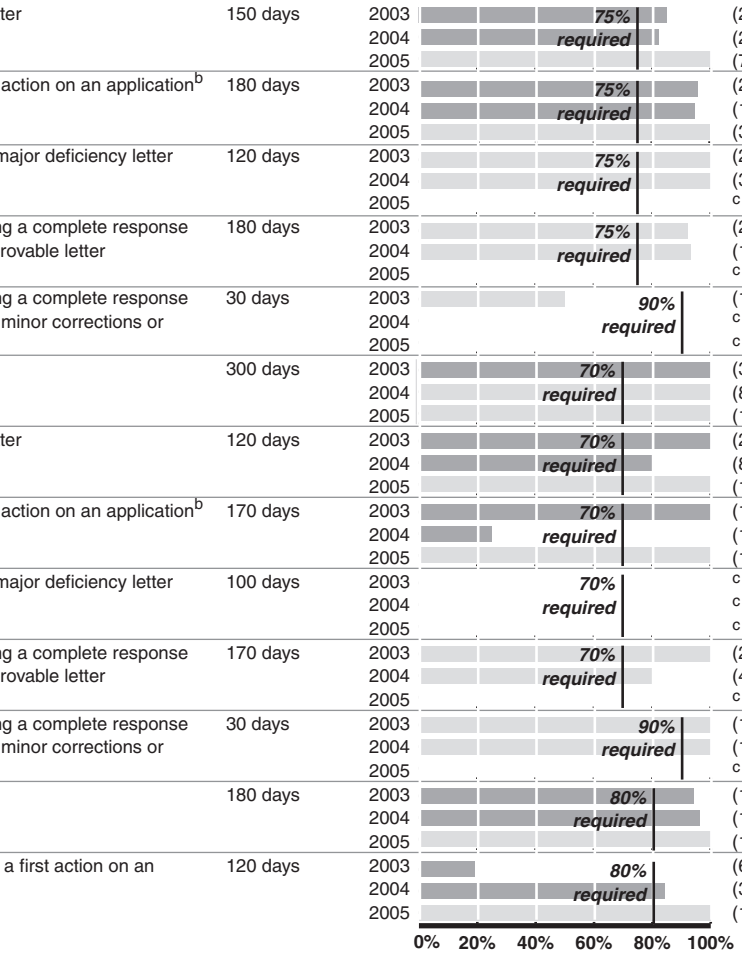
The limited data available indicate that FDA has been meeting some MDUFMA performance goals established for fiscal year 2005. It is uncertain, however, whether FDA will ultimately meet the fiscal year 2005 performance goals once reviews for all the applications are complete. We found that FDA met most of the MDUFMA fiscal year 2005 performance goals for which there were sufficiently complete data to measure the agency's performance. When FDA did not have sufficiently complete data to evaluate performance against a MDUFMA performance goal, we reviewed preliminary data and found that FDA took actions tied to most of these other fiscal year 2005 goals within specified time frames. Data from the first 6 months of fiscal year 2005 are not sufficiently complete to evaluate FDA's performance against MDUFMA performance goals because some applications are pending review and because manufacturers are likely to submit additional applications and amendments for review.

Our analysis shows that FDA met most of the MDUFMA 2005 performance goals for which there were sufficiently complete data to measure performance (see fig. 4). These data were from applications that FDA received in fiscal years 2003 and 2004 and were used to measure the agency's performance against about half of the performance goals established for fiscal year 2005. As of March 31, 2005, FDA had sufficiently complete data from applications received in fiscal year 2003 to measure performance against 11 of the 20 goals established for fiscal year 2005. FDA met 9 of those 11 goals and did not meet 2 of them. For applications received in fiscal year 2004, FDA had sufficiently complete data to measure performance against 10 of the 20 goals. It met 9 and did not meet 1 of these goals. For example, one of FDA's 2005 performance goals requires the agency to issue a first major deficiency letter within 150 days for 75 percent of PMAs, Panel-Track Supplements, and Premarket Reports that the agency received during the fiscal year and found to be incomplete. For applications in the fiscal year 2003 and 2004 cohorts, respectively, FDA issued 22 of 26 (85 percent) and 23 of 28 (82 percent) first major deficiency letters within 150 days, thus meeting the goal. FDA had complete data on its performance against this performance goal from both the fiscal year 2003 and 2004 cohorts—there were no other applications that FDA received during these years for which a first major deficiency letter can be issued. Figure 4 also shows that FDA had sufficiently complete data on applications received in both fiscal years 2003 and 2004 on 2 performance goals established for fiscal year 2005 that are tied to 510(k) applications, the type of MDUFMA-related medical device application that FDA receives most frequently. These data indicate that FDA met 1 of the 2 goals with applications received in fiscal year 2003 and met both goals for applications received in fiscal year 2004. Sufficiently

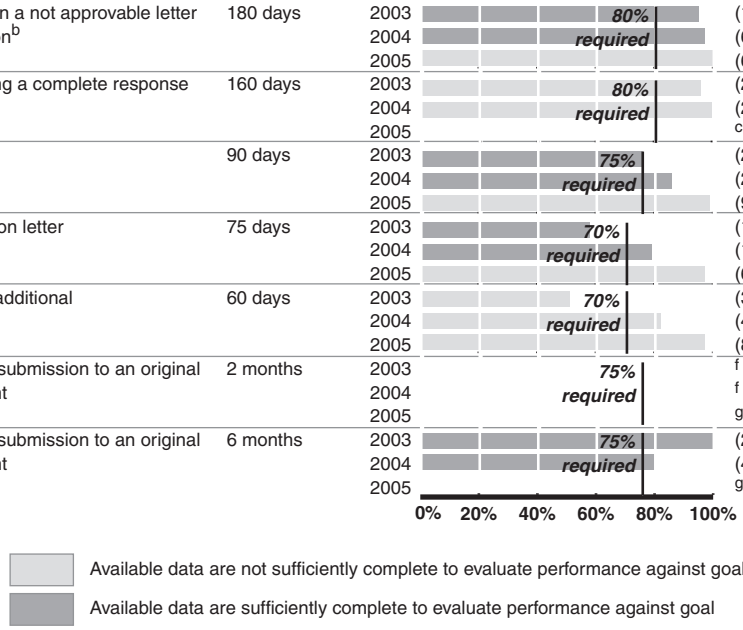
complete data were also available on applications received in fiscal years 2003 and 2004 to evaluate FDA's performance on 3 of the 2005 performance goals tied to 180-Day PMA Supplements, the type of MDUFMA-related application that FDA receives second most frequently. FDA met 2 of these 3 goals on applications received in 2003 and met the 3 goals on applications received in 2004.

Figure 4: FDA's Performance as of March 31, 2005, for Applications Received in Fiscal Years 2003, 2004, and 2005 as Measured against MDUFMA Performance Goals Established for Fiscal Year 2005

Type of application	Actions, including decisions	Performance goal's review time	Percentage of actions taken within goal's review time as of March 31, 2005, for applications received in fiscal years 2003, 2004, and 2005 as measured against performance goals for fiscal year 2005	
PMAs, Panel-Track Supplements, and Premarket Reports[a]	Issue a first major deficiency letter	150 days	2003 2004 2005	(22 of 26 actions) (23 of 28 actions) (7 of 7 actions)
	Issue a decision letter as a first action on an application[b]	180 days	2003 2004 2005	(23 of 24 actions) (19 of 20 actions) (3 of 3 actions)
	Issue a second or subsequent major deficiency letter	120 days	2003 2004 2005	(2 of 2 actions) (3 of 3 actions) c
	Act on an amendment containing a complete response to a major deficiency or not approvable letter	180 days	2003 2004 2005	(23 of 25 actions) (14 of 15 actions) c
	Act on an amendment containing a complete response to an approvable letter pending minor corrections or clarifications[d]	30 days	2003 2004 2005	(1 of 2 actions) c c
Expedited PMAs	Issue a decision letter[b]	300 days	2003 2004 2005	(3 of 3 decisions) (8 of 8 decisions) (1 of 1 decision)
	Issue a first major deficiency letter	120 days	2003 2004 2005	(2 of 2 actions) (8 of 10 actions) (1 of 1 action)
	Issue a decision letter as a first action on an application[b]	170 days	2003 2004 2005	(1 of 1 action) (1 of 4 actions) (1 of 1 action)
	Issue a second or subsequent major deficiency letter	100 days	2003 2004 2005	c c c
	Act on an amendment containing a complete response to a major deficiency or not approvable letter	170 days	2003 2004 2005	(2 of 2 actions) (4 of 5 actions) c
	Act on an amendment containing a complete response to an approvable letter pending minor corrections or clarifications[d]	30 days	2003 2004 2005	(1 of 1 action) (1 of 1 action) c
180-Day PMA Supplements	Issue a decision letter[b]	180 days	2003 2004 2005	(194 of 206 decisions) (102 of 106 decisions) (18 of 18 decisions)
	Issue a not approvable letter as a first action on an application	120 days	2003 2004 2005	(6 of 32 actions) (36 of 43 actions) (11 of 11 actions)



Type of application	Actions, including decisions	Performance goal's review time	Percentage of actions taken within goal's review time as of March 31, 2005, for applications received in fiscal years 2003, 2004, and 2005 as measured against performance goals for fiscal year 2005	
180-Day PMA Supplements (cont'd)	Issue a decision letter other than a not approvable letter as a first action on an application[b]	180 days	2003	(166 of 174 actions)
			2004	(61 of 63 actions)
			2005	(6 of 6 actions)
	Act on an amendment containing a complete response to a not approvable letter	160 days	2003	(23 of 24 actions)
			2004	(27 of 27 actions)
			2005	[c]
510(k)s	Issue a decision letter[e]	90 days	2003	(2,887 of 3,790 decisions)
			2004	(2,802 of 3,267 decisions)
			2005	(920 of 933 decisions)
	Issue a first additional information letter	75 days	2003	(1,005 of 1,719 actions)
			2004	(1,271 of 1,618 actions)
			2005	(639 of 659 actions)
	Issue a second or subsequent additional information letter	60 days	2003	(311 of 610 actions)
			2004	(448 of 546 actions)
			2005	(88 of 91 actions)
BLA Resubmissions and BLA Efficacy Supplement Resubmissions	Review and act on a Class 1 resubmission to an original BLA or BLA efficacy supplement	2 months	2003	[f]
			2004	[f]
			2005	[g]
	Review and act on a Class 2 resubmission to an original BLA or BLA efficacy supplement	6 months	2003	(2 of 2 actions)
			2004	(4 of 5 actions)
			2005	[g]



Source: GAO analysis of FDA data.

Note: FDA's data for some MDUFMA performance goals are not complete because applications are pending within the review process or because manufacturers can submit additional applications or amendments to their applications. We defined the data as sufficiently complete to evaluate performance when we could determine whether FDA would or would not meet the performance goal. In contrast, when FDA's data were not sufficiently complete to evaluate performance, we considered data on FDA's performance to be preliminary. The performance goals established for fiscal year 2005 did not include any goals tied to BLAs or BLA Supplements.

[a]FDA groups these types of applications when measuring performance for this goal. FDA did not receive any Premarket Reports in fiscal years 2003 or 2004 or the first 6 months of fiscal year 2005.

[b]A decision letter for a PMA, Panel-Track Supplement, Premarket Report, Expedited PMA, or 180-Day PMA Supplement can indicate approval, approvable pending GMP inspection, approvable pending minor corrections or clarifications, not approvable, or denial.

[c]As of March 31, 2005, FDA had not received any submissions that required the agency to take the action tied to the performance goal. It could subsequently receive submissions.

[d]This performance goal had also been established for fiscal years 2003 and 2004 and required 90 percent of actions to be taken within 30 days.

[e]A decision letter for a 510(k) can indicate that the device may be marketed because it is substantially equivalent to one already on the market or may not be marketed because it is not substantially equivalent.

[f]FDA did not receive any submissions that required the agency to take the action tied to the performance goal. No additional submissions are possible.

[g]As of March 31, 2005, FDA had received submissions tied to the performance goal, but had not taken any actions tied to the goal. FDA could subsequently receive additional submissions.

As figure 4 shows, FDA's data from applications received in fiscal years 2003 and 2004 and the first 6 months of fiscal year 2005 are not sufficiently complete to evaluate the agency's performance against some fiscal year 2005 goals. The preliminary data available on these goals suggest that when FDA took actions tied to fiscal year 2005 performance goals, it generally did so within specified time frames.[15] As of March 31, 2005, FDA had preliminary data from applications received in fiscal year 2003 on 7 of the 9 performance goals for fiscal year 2005 for which data were not sufficiently complete to evaluate performance. FDA took actions tied to 5 of the 7 goals within the specified time frames. For applications received in fiscal year 2004, FDA had preliminary data for 7 of the 10 performance goals for which data were not sufficiently complete, and the agency took actions tied to these 7 goals within the specified time frames. FDA also had preliminary performance data from applications received in the first 6 months of fiscal year 2005 for 11 of the 20 goals. FDA took actions tied to these 11 goals within the specified time frames. These preliminary results could change as FDA completes its review of pending applications and additional applications or amendments. For example, one of FDA's 2005 performance goals for expedited PMAs was to take action within 170 days for 70 percent of amendments containing complete responses to a major deficiency or not approvable letter. As of March 31, 2005, FDA had taken action within 170 days on two of two such amendments (100 percent) to applications in the fiscal year 2003 cohort and four of five (80 percent) in the fiscal year 2004 cohort and had received no such amendments for applications in the fiscal year 2005 cohort. These preliminary performance results could change, however, if manufacturers submit additional amendments to applications in any of the three cohorts.

Based on the limited data that were available as of March 31, 2005, it is unclear whether or to what extent FDA will meet the fiscal year 2005 MDUFMA performance goals because the agency's performance could change as the agency completes its review of applications. For example, some applications are pending review because FDA has not reached a

[15]FDA did not have data on a performance goal if the agency had not received any applications of the type that is tied to that goal or if the agency had received applications of that type but had not taken any of the actions tied to the goal as of March 31, 2005.

decision about the application or because the manufacturer has not responded to a letter from FDA indicating that the application included insufficient information for FDA to complete its review. Our analysis shows that as of March 31, 2005, about half of the applications FDA had received during the first 6 months of fiscal year 2005—831 of 1,792—were pending. (See table 2, which also shows the number of pending applications from the fiscal year 2003 and 2004 cohorts.) The percentage of pending applications varied by application type. For example, for the fiscal year 2005 cohort, 22—95.7 percent—of 23 PMAs and Panel-Track Supplements were pending further action, while 4—33.3 percent—of 12 BLA Supplements were pending.

Table 2: Applications Received in Fiscal Years 2003 and 2004 and the First 6 Months of Fiscal Year 2005 That Were Pending Further Action as of March 31, 2005

	Fiscal year 2003		Fiscal year 2004		First 6 months of fiscal year 2005	
Type of application	**Total number of applications**	**Number (percentage) pending**	**Total number of applications**	**Number (percentage) pending**	**Total number of applications**	**Number (percentage) pending**
PMA and Panel-Track Supplements	50	5 (10.0%)	48	13 (27.1%)	23	22 (95.7%)
Expedited PMAs	3	0 (0.0%)	14	6 (42.9%)	3	2 (66.7%)
180-Day PMA Supplements	206	0 (0.0%)	106	0 (0.0%)	45	27 (60.0%)
510(k)s	3,805	15 (0.4%)	3,432	165 (4.8%)	1,703	770 (45.2%)
BLAs	0	0 (0.0%)	9	1 (11.1%)	1	1 (100.0%)
BLA Supplements	78	0 (0.0%)	96	0 (0.0%)	12	4 (33.3%)
BLA Resubmissions and BLA Efficacy Supplement Resubmissions	2	0 (0.0%)	5	0 (0.0%)	5	5 (100%)
Total	**4,144**	**20 (0.5%)**	**3,710**	**185 (5.0%)**	**1,792**	**831 (46.4%)**

Source: GAO analysis of FDA data.

Note: FDA did not receive any Premarket Reports in fiscal years 2003 or 2004 or in the first 6 months of fiscal year 2005.

As previously noted, FDA's preliminary performance results could also change if manufacturers submit additional applications or amendments, as is likely. For example, FDA received 1,703 510(k) applications during the first 6 months of fiscal year 2005, about half the number it received in each of the 2 preceding full fiscal years (3,805 and 3,432 for fiscal years 2003 and 2004, respectively). These data suggest that as of March 31, 2005, FDA had received about half of the 510(k) applications that it may receive in fiscal year 2005. Similarly, performance results for applications FDA received in fiscal years 2003, 2004, and 2005 could change as manufacturers respond to requests for additional information or submit amendments to their applications. For example, as of March 31, 2005, FDA had issued letters requesting additional information for 659 of the 510(k) applications it received during the first 6 months of fiscal year 2005. It is likely that FDA will receive responses to these requests from manufacturers.

Limited Available Data Suggest That FDA is Likely to Meet Some Performance Goals Established for Fiscal Year 2006

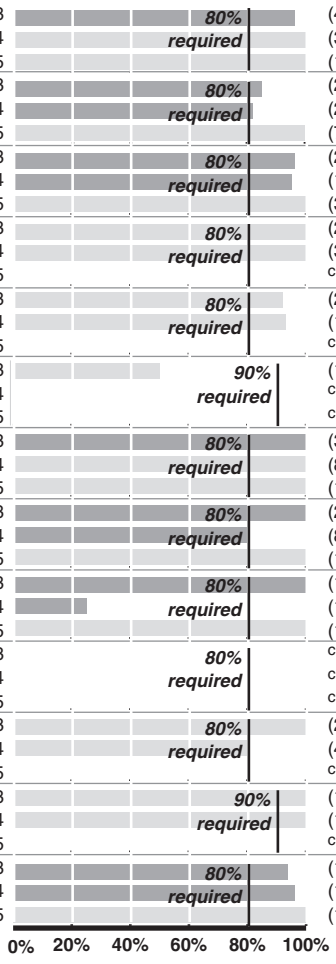
The limited data available on FDA's performance suggest that FDA is likely to meet some of its fiscal year 2006 performance goals. Our analysis of FDA's performance for applications received in fiscal years 2003 and 2004 shows that FDA has been meeting most of the MDUFMA 2006 performance goals for which it had sufficiently complete data. We also reviewed FDA's preliminary data from applications received in fiscal years 2003 and 2004 and the first 6 months of fiscal year 2005, and found that FDA took actions tied to most of the remaining fiscal year 2006 goals within specified time frames. Preliminary performance results could change as the agency completes actions for applications received in fiscal years 2003, 2004, and 2005 and FDA's performance could change as it receives applications in fiscal year 2006. FDA has taken several steps to help meet the MDUFMA performance goals.

Our analysis of FDA's past performance shows that FDA met most, but not all, of the MDUFMA 2006 performance goals for which it had sufficiently complete data. (See fig. 5.) As of March 31, 2005, FDA had sufficiently complete data from applications received in fiscal year 2003 to measure performance against 14 of 26 goals established for fiscal year 2006. FDA met 12 of those 14 goals. FDA also had sufficiently complete data from applications received in fiscal year 2004 to measure performance against 12 performance goals and met 9 of those 12 goals. Figure 5 also shows that FDA had sufficiently complete data from both fiscal years 2003 and 2004 on 2 performance goals established for fiscal year 2006 that are tied to 510(k) applications, the type of MDUFMA-related medical device application that FDA receives most frequently. These data indicate that

FDA met 1 of the 2 goals for applications received in both fiscal years 2003 and 2004. Sufficiently complete data were available for applications received in fiscal years 2003 and 2004 to evaluate performance on 3 of the 2006 performance goals tied to 180-Day PMA Supplements, the type of MDUFMA-related application that FDA receives second most frequently. FDA met 2 of these 3 goals on applications received in both fiscal years.

Figure 5: FDA's Performance as of March 31, 2005, for Applications Received in Fiscal Years 2003, 2004, and 2005 as Measured against MDUFMA Performance Goals Established for Fiscal Year 2006

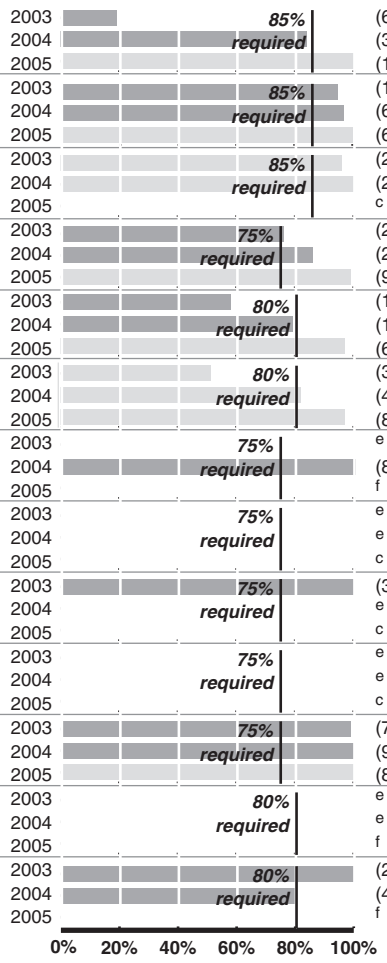
Type of application	Actions, including decisions	Performance goal's review time	Percentage of actions taken within goal's review time as of March 31, 2005, for applications received in fiscal years 2003, 2004, and 2005 as measured against performance goals for fiscal year 2006
PMAs, Panel-Track Supplements, and Premarket Reports[a]	Issue a decision letter[b]	320 days	2003 (43 of 45 decisions) 2004 (35 of 35 decisions) 2005 (1 of 1 decisions)
	Issue a first major deficiency letter	150 days	2003 (22 of 26 actions) 2004 (23 of 28 actions) 2005 (7 of 7 actions)
	Issue a decision letter as a first action on an application[b]	180 days	2003 (23 of 24 actions) 2004 (19 of 20 actions) 2005 (3 of 3 actions)
	Issue a second or subsequent major deficiency letter	120 days	2003 (2 of 2 actions) 2004 (3 of 3 actions) 2005 [c]
	Act on an amendment containing a complete response to a major deficiency or not approvable letter	180 days	2003 (23 of 25 actions) 2004 (14 of 15 actions) 2005 [c]
	Act on an amendment containing a complete response to an approvable letter pending minor corrections or clarifictions	30 days	2003 (1 of 2 actions) 2004 [c] 2005 [c]
Expedited PMAs	Issue a decision letter[b]	300 days	2003 (3 of 3 decisions) 2004 (8 of 8 decisions) 2005 (1 of 1 decision)
	Issue a first major deficiency letter	120 days	2003 (2 of 2 actions) 2004 (8 of 10 actions) 2005 (1 of 1 action)
	Issue a decision letter as a first action on an application[b]	170 days	2003 (1 of 1 action) 2004 (1 of 4 actions) 2005 (1 of 1 action)
	Issue a second or subsequent major deficiency letter	100 days	2003 [c] 2004 [c] 2005 [c]
	Act on an amendment containing a complete response to a major deficiency or not approvable letter	170 days	2003 (2 of 2 actions) 2004 (4 of 5 actions) 2005 [c]
	Act on an amendment containing a complete response to an approvable letter pending minor corrections or clarifications	30 days	2003 (1 of 1 action) 2004 (1 of 1 action) 2005 [c]
180-Day PMA Supplements	Issue a decision letter[b]	180 days	2003 (194 of 206 decisions) 2004 (102 of 106 decisions) 2005 (18 of 18 decisions)



Available data are not sufficiently complete to evaluate performance against goal

Available data are sufficiently complete to evaluate performance against goal

Type of application	Actions, including decisions	Performance goal's review time	Percentage of actions taken within goal's review time as of March 31, 2005, for applications received in fiscal years 2003, 2004, and 2005 as measured against performance goals for fiscal year 2006
180-Day PMA Supplements (cont'd)	Issue a not approvable letter as a first action on an application	120 days	2003 (6 of 32 actions) 2004 (36 of 43 actions) 2005 (11 of 11 actions)
	Issue a decision letter other than a not approvable letter as a first action on an application[b]	180 days	2003 (166 of 174 actions) 2004 (61 of 63 actions) 2005 (6 of 6 actions)
	Act on an amendment containing a complete response to a not approvable letter	160 days	2003 (23 of 24 actions) 2004 (27 of 27 actions) 2005 [c]
510(k)s	Issue a decision letter[b]	90 days	2003 (2,887 of 3,790 decisions) 2004 (2,802 of 3,267 decisions) 2005 (920 of 933 decisions)
	Issue a first additional information letter	75 days	2003 (1,005 of 1,719 actions) 2004 (1,271 of 1,618 actions) 2005 (639 of 659 actions)
	Issue a second or subsequent additional information letter	60 days	2003 (311 of 610 actions) 2004 (448 of 546 actions) 2005 (88 of 91 actions)
BLAs	Review and act on a standard original BLA	10 months	2003 [e] 2004 (8 of 8 actions) 2005 [f]
	Review and act on a priority original BLA	6 months	2003 [e] 2004 [e] 2005 [c]
BLA Supplements	Review and act on a standard BLA efficacy supplement	10 months	2003 (3 of 3 actions) 2004 [e] 2005 [c]
	Review and act on a priority BLA efficacy supplement	6 months	2003 [e] 2004 [e] 2005 [c]
	Review and act on a BLA manufacturing supplement that requires prior approval	4 months	2003 (74 of 75 actions) 2004 (96 of 96 actions) 2005 (8 of 8 actions)
BLA Resubmissions and BLA Efficacy Supplement Resubmissions	Review and act on a Class 1 resubmission to an original BLA or BLA efficacy supplement	2 months	2003 [e] 2004 [e] 2005 [f]
	Review and act on a Class 2 resubmission to an original BLA or BLA efficacy supplement	6 months	2003 (2 of 2 actions) 2004 (4 of 5 actions) 2005 [f]



Available data are not sufficiently complete to evaluate performance against goal

Available data are sufficiently complete to evaluate performance against goal

Source: GAO analysis of FDA data.

Note: FDA's data for some MDUFMA performance goals are not complete because applications are pending within the review process or because manufacturers can submit additional applications or amendments to their applications. We defined the data as sufficiently complete to evaluate performance when we could determine whether FDA would or would not meet the performance goal. In contrast, when FDA's data were not sufficiently complete to evaluate performance, we considered data on FDA's performance to be preliminary.

[a]FDA groups these types of applications when measuring performance for this goal. FDA did not receive any Premarket Reports in fiscal years 2003 or 2004 or the first 6 months of fiscal year 2005.

[b]A decision letter for a PMA, Panel-Track Supplement, Premarket Report, Expedited PMA, or 180-Day PMA Supplement can indicate approval, approvable pending GMP inspection, approvable pending minor corrections or clarifications, not approvable, or denial.

[c]As of March 31, 2005, FDA had not received any submissions that required the agency to take the action tied to the performance goal. It could subsequently receive submissions.

[d]A decision letter for a 510(k) can indicate that the device may be marketed because it is substantially equivalent to one already on the market or may not be marketed because it is not substantially equivalent.

[e]FDA did not receive any submissions that required the agency to take the action tied to the performance goal. No additional submissions are possible.

[f]As of March 31, 2005, FDA had received submissions tied to the performance goal, but had not taken any actions tied to the goal. FDA could subsequently receive additional submissions.

Figure 5 also shows that preliminary performance data from applications received in fiscal years 2003 and 2004 and the first 6 months of fiscal year 2005 indicate that FDA took actions tied to most of the remaining fiscal year 2006 performance goals within specified time frames. Of 12 performance goals for which data on applications received in fiscal year 2003 were not sufficiently complete to evaluate performance, FDA had preliminary data on 7. FDA took actions tied to 5 of these 7 goals within the specified time frames. Of 14 performance goals for which FDA did not have sufficiently complete data from applications received in fiscal year 2004, FDA had preliminary data for 8 and took actions tied to these 8 goals within the specified time frames. FDA had preliminary data from applications received in the first 6 months of fiscal year 2005 for 13 of the 26 goals established for fiscal year 2006. FDA took actions tied to these 13 goals within the established time frames. These performance results could change as the agency completes actions for applications received in fiscal years 2003, 2004, and 2005 and FDA's performance could change as it receives applications in fiscal year 2006.

In general, when sufficient data indicated that FDA's performance results for applications received in a fiscal year met the performance goal established for fiscal year 2005, then the agency also met the performance goal established for fiscal year 2006, even when the 2006 goal required FDA to take action within specified time frames on a greater percentage of applications. There were two exceptions that involved issuing not

approvable letters as a first action on 180-Day PMA Supplements received in fiscal year 2004 and issuing additional information letters as a first action for 510(k)s received in fiscal year 2004. In each of these cases, FDA met the performance goal established for fiscal year 2005, but did not meet the goal established for fiscal year 2006.

To help meet its MDUFMA performance goals, FDA has taken several steps consistent with those outlined by the Secretary of Health and Human Services in his November 2002 letter establishing those goals. For example, FDA issued additional guidance to manufacturers on topics related to medical device applications in fiscal year 2004 and 2005. To help implement MDUFMA, CDRH hired 55 new staff (such as medical officers, scientists, and engineers) in fiscal year 2004 and 44 new staff in fiscal year 2005. According to FDA, prior to the enactment of the Medical Device User Fee Stabilization Act of 2005,[16] there was uncertainty about the continuation of the MDUFMA program, and as a result, most of these new employees were hired on a temporary basis. Moreover, CDRH instituted a hiring freeze for MDUFMA-related positions in May 2005. FDA also said that as a consequence of hiring fewer personnel than planned to perform tasks associated with the MDUFMA program, implementation of improvements FDA intended to make was constrained. For example, fewer new guidance documents were drafted, fewer existing guidance documents were updated, and the modernization of data systems proceeded at a slower pace than FDA intended. An FDA spokesman told us that CDRH may lift its freeze on hiring new staff by the start of fiscal year 2006.

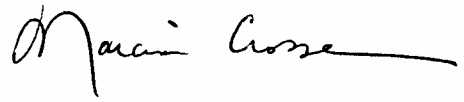
Agency Comments

In written comments on a draft of this report, FDA concurred with our findings. FDA also provided clarifying technical comments, which we incorporated. FDA's comments are reprinted in appendix I.

We are sending copies of this report to the Secretary of Health and Human Services and the Acting Commissioner of FDA, appropriate congressional committees, and other interested parties. We will also make copies available to others on request. In addition, the report is available at no charge on the GAO Web site at http://www.gao.gov. If you or your staffs have questions about this report, please contact me at (202) 512-7119 or

[16]Pub. L. No. 109-43, § 2(a)(5), 119 Stat. 439, 440.

crossem@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix II.



Marcia Crosse
Director, Health Care

Appendix I: Comments from the Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

September 26, 2005

Marcia Crosse
Director, Health Care
United States Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Crosse:

FDA found the draft report entitled, *"FOOD AND DRUG ADMINISTRATION: Limited Available Data Indicate that FDA Has Been Meeting Some Goals for Review of Medical Device Applications (GAO-05-1042)"* to be well-written, well-organized, and accurate in its descriptions of FDA's medical device review programs, the performance goals we are pursuing under MDUFMA, and our progress towards achieving those goals. GAO's findings are fair and accurate, and acknowledge the progress we have made, the obstacles we have encountered, and the uncertainties that still exist.

We appreciate the opportunity to review and comment on this draft report before it is published, as well as the opportunity to work with your staff in its development.

Sincerely,

Janet Woodcock, M.D.
Deputy Commissioner for Operations

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

Marcia Crosse, (202) 512-7119 or crossem@gao.gov

Acknowledgments

In addition to the contact named above, James McClyde, Assistant Director, and Kristen Joan Anderson made key contributions to this report.

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