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United States Government Accountability Office
Washington, DC 20548

April 18, 2012

The Honorable Richard Burr
Ranking Member
Subcommittee on Children and Families
Committee on Health Education Labor and Pensions
United States Senate

The Honorable Tom Coburn
Ranking Member
Permanent Subcommittee on Investigations
Committee on Homeland Security and Governmental Affairs
United States Senate

Subject: *Food and Drug Administration: Employee Performance Standards for the Timely Review of Medical Product Applications*

This report formally transmits the attached briefing in response to your request that we provide information on the standards that the Food and Drug Administration (FDA) considers when assessing the performance of its employees. (See the enclosure.) You asked whether the agency's timeliness goals for processing medical product applications are reflected in the performance standards for FDA employees who have a role in reviewing these applications. These timeliness goals are one aspect that FDA may consider in assessing employee performance. The extent to which these goals are reflected as explicit expectations in employee performance standards varies by an employee's duties, level of responsibility, and organizational component. We provided the briefing to your staff on April 17, 2012.

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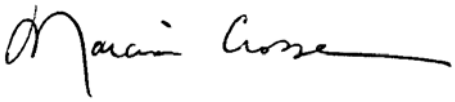
As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Commissioner of FDA and appropriate congressional committees. The report also will be available at no charge on the GAO website at http://www.gao.gov.

If you or your staff have any questions regarding this report, please contact me at (202) 512- 7114 or crossem@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Key contributions to this report were made by Geri Redican-Bigott, Assistant Director; Kelly DeMots; Cathleen Hamann; Hannah Marston Minter; and Lisa Motley.



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Director, Health Care

Enclosure

Food and Drug Administration: Employee Performance Standards for the Timely Review of Medical Product Applications

Briefing for the staff of

The Honorable Richard Burr
Ranking Member
Subcommittee on Children and Families
Committee on Health, Education, Labor, and Pensions
United States Senate

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April 17, 2012

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Introduction

- The Food and Drug Administration (FDA) is responsible for overseeing the safety and efficacy of medical products—drugs, devices, and biological products—sold in the United States. Sponsors of these products submit applications to FDA for review.* FDA approval or clearance is generally required before marketing.
- In 2007, Congress reauthorized the two user fee programs under which FDA receives resources to support the process of reviewing applications for new medical products through the Prescription Drug User Fee Amendments (PDUFA) and the Medical Device User Fee Amendments (MDUFA).

*We use the term "application" to include applications, submissions, and notifications related to medical product review.

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Introduction

- PDUFA and MDUFA provide for funding for FDA through user fees collected from the sponsors of new medical products for fiscal years 2008 through 2012.
- Under PDUFA and MDUFA, FDA committed to performance goals in order to ensure the timely review of certain new medical product applications.
- The details of these agency performance goals are negotiated between FDA and industry stakeholders, and include specific time frames within which FDA is to take action on a certain percentage of applications.

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Introduction

- FDA employees who review medical product applications may include biologists, chemists, engineers, medical doctors, microbiologists, pharmacologists, statisticians, and other experts.
- In addition, some officers of the U.S. Public Health Service Commissioned Corps are stationed at FDA. Commissioned Corps officers may serve in a variety of federal agencies in various capacities, including disease control and prevention, biomedical research, and health care delivery. Officers stationed at FDA—like FDA employees—may review medical product applications.

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Introduction

- We recently reported on FDA's timeliness in meeting performance goals related to its review of medical devices. As part of that report, we found that FDA had not met a subset of these performance goals.*

*See GAO, *Medical Devices: FDA Has Met Most Performance Goals but Device Reviews Are Taking Longer*, GAO-12-418 (Washington, D.C.: Feb. 29, 2012).

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Objective

- Given FDA's commitment to meeting specific performance goals, you asked whether these agency goals are included in employee performance standards. This briefing examines the extent to which FDA includes the timeliness of new medical product application reviews in standards used to assess employee performance, including any mention of PDUFA- or MDUFA-related goals.

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Scope and Methodology

- We reviewed documentation of standards for employee performance for three centers at FDA—the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Center for Devices and Radiological Health (CDRH). These centers identified the employee positions involved with new medical product application reviews.

- Specifically, we reviewed standards for employee performance which are contained in employee performance plan templates. These templates are standardized by employee position and maintained separately by each center. The centers may customize these templates to create individual performance plans for each employee.

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Scope and Methodology

- We interviewed officials from FDA, including officials from CDER, CBER, and CDRH. Because officers of the U.S. Public Health Service Commissioned Corps may be stationed at FDA and involved in medical product application reviews, we also interviewed an officer of the Commissioned Corps.

- We also reviewed other relevant materials, including laws and FDA and Commissioned Corps policies.

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Scope and Methodology

- We conducted our work from March 2012 through April 2012 in accordance with all sections of GAO's Quality Assurance Framework. The framework requires that we plan and perform the engagement to obtain sufficient and appropriate evidence to meet our stated objectives and to discuss any limitations in our work. We believe that the information and data obtained, and the analysis conducted, provide a reasonable basis for any findings and conclusions in this product.

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Background

FDA Medical Product Application Review

- Medical product applications—including new drug and device applications—are reviewed by employees in CDER, CBER, and CDRH. These staff include executive and nonexecutive employees from FDA as well as members of the U.S. Public Health Service Commissioned Corps stationed at FDA.

- Not all applications, such as those for generic drugs, are subject to user fees and the performance goals associated with PDUFA and MDUFA.

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Background

FDA Medical Product Application Review (cont.)

- FDA receives a variety of applications for medical products for which the agency is subject to PDUFA or MDUFA performance goals. These goals vary based on the type of application, which can include
  - Applications for new drugs, medical devices, and biologics–such as New Drug Applications (NDA), Premarket Approvals (PMA), Premarket Notifications (510(k)s), and Biologics License Applications (BLA).
  - Applications to modify existing medical products, or supplements to modify the use or manufacturing of medical products.
- Drug applications subject to PDUFA may be reviewed in CDER. Device applications subject to MDUFA may be reviewed in CDRH. Applications with a biological component that are subject to either PDUFA or MDUFA may be reviewed in CBER.

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Background

Goals Associated with PDUFA and MDUFA

PDUFA Review Performance Goals, FY 2008-2012

Type of application	Performance goal
Priority original NDAs, BLAs, and efficacy supplements	90% within 6 months of receipt
Standard original NDAs, BLAs, and efficacy supplements	90% within 10 months of receipt
Manufacturing supplements	90% within 6 months of receipt and those requiring prior approval within 4 months of receipt
Class 1 resubmitted original NDAs, BLAs, and efficacy supplements	90% within 2 months of receipt
Class 2 resubmitted original NDAs, BLAs, and efficacy supplements	90% within 6 months of receipt

Source: GAO analysis of FDA data.

MDUFA Review Performance Goals, FY 2008-2012

Type of application	Performance goal
Original PMAs, Panel-Track Supplements, and Premarket Reports	60% within 180 days 90% within 295 days
Expedited Original PMAs and Panel-Track PMA Supplements	50% within 180 days 90% within 280 days
PMA Modules	75% within 90 days 90% within 120 days
180-day PMA Supplements	85% within 180 days 95% within 210 days
Real-Time PMA Supplements	80% within 60 days 90% within 90 days
510(k)s	90% within 90 days 98% within 150 days

Source: GAO analysis of FDA data.

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Background

FDA Employee Performance Assessment

- Most federal agencies' performance management systems are subject to review by the Office of Personnel Management (OPM). OPM reviews these systems to ensure they meet statutory and regulatory requirements.
- The Department of Health and Human Services (HHS) has established a performance management system for its component agencies, including FDA. HHS's system has been reviewed by OPM.
  - HHS provides FDA with a framework for the agency to develop its employees' performance plans.
  - Centers within FDA develop templates for employee performance plans.

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Background

FDA Employee Performance Assessment (cont.)

- FDA conducts performance assessments of its employees on an annual cycle.
- Staff involved in the review of medical product applications—with the exception of the Commissioned Corps—develop performance plans with their managers at the beginning of a performance cycle, and are assessed at the end of a cycle based on the standards in the performance plan, depending on whether they are an executive employee—such as a Center Director—or a nonexecutive employee.

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Background

FDA Employee Performance Assessment (cont.)

- FDA's performance management system is decentralized and paper-based.
  - Information, including standards from individual employees' performance plans and their subsequent annual assessments, is not stored in a single place or available in electronic format.
  - High-level summary information on employee performance may be tracked separately by managers within FDA centers using various software programs.

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Background

FDA Employee Performance Assessment: Executives

- Executive employees' performance plans can contain up to seven standards on which executive employees are assessed.
  - Two of these standards are required for executive employees in HHS: (1) Executive Leadership, and (2) Management.
  - Up to five of these standards can be customized by their supervisors as needed. For example, one performance plan might include: Improve the Quality of Medical Devices, Advance a Total Life Cycle Approach to Medical Devices, and Advance FDA's Global Product Safety Strategy. Another might include: Performance Culture, Supervisory Procedures, Communication, and Technical Competency.

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Background

FDA Employee Performance Assessment: Nonexecutives

- Nonexecutive employees' performance plans can have up to six standards on which an employee is assessed.
  - One of these standards is required for nonexecutive employees in HHS: Administrative Requirements.
  - Up to five of these standards can be customized by their supervisors as needed. For example, one performance plan might include: Strategic Direction, Leadership/Motivational Skills, and Communication. Another might include: Data Analysis and Evaluation, Technical Expertise, Customer Service, and Advice.

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Background

FDA Employee Performance Assessment: Commissioned Corps

- Commissioned Corps officers are not required to have performance plans, but some officers may have such plans at their supervisors' discretion.

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Results

Employee Performance Standards for the Timely Review of Medical Product Applications

- Timeliness One Aspect of Employee Performance Assessments
- Timeliness Standards for Center Directors, Other Executive Employees, and Nonexecutive Employees
- Timeliness Standards for Commissioned Corps Officers

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FDA Employee Performance Standards

Timeliness One Aspect of Employee Performance Assessments

- FDA officials told us that,
  - The timeliness of application reviews is one aspect of employee performance, and it is also important to balance timeliness with the agency's standards for medical product safety and effectiveness.
  - Assessing employee performance based solely on timeliness is inappropriate because, for example, more difficult applications could be associated with longer review times.
  - Multiple employees are responsible for the review of a single application, and it is not any one employee's responsibility to meet the goals related to PDUFA and MDUFA.

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FDA Employee Performance Standards

Timeliness Standards for Center Directors

- FDA officials told us that the Center Directors in CDER, CBER, and CDRH—who are executive employees—are ultimately accountable for meeting the timelines related to the PDUFA and MDUFA performance goals—including the percentages of reviews conducted within designated time frames.

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FDA Employee Performance Standards

Timeliness Standards for Center Directors (cont.)

- Performance plans for two of three Center Directors explicitly included timeliness goals related to PDUFA or MDUFA. The performance plan for the CDRH Director included general language about timeliness.

- Performance plans for all three Center Directors included management standards that stated that the employees should hold themselves and others "accountable for measurable, high-quality, timely, and cost-effective results."

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FDA Employee Performance Standards

Timeliness Standards for Center Directors (cont.)

- For example,
  - The performance plan for the CDER Director included language specific to PDUFA under a standard titled “Advancing Medical Product Safety and Effectiveness.” This plan stated that the Director is expected to achieve a target of 90 percent completion of standard reviews within 10 months, and achieve a target of 90 percent completion of priority reviews within 6 months, consistent with PDUFA goals.
  - The performance plan for the CBER Director included language specific to MDUFA and PDUFA under a standard titled “Access to Safe and Effective New Products.” The performance plan stated that the Director is expected to achieve a target of 90 percent completion of standard and priority BLA/NDA reviews within specified time frames and to achieve a target of 90 percent completion of 510(k) reviews within 90 days.

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FDA Employee Performance Standards

Timeliness Standards for Other Executive Employees

- Timeliness standards were included in all 18 performance plans for other executive employees in CDER, CBER, and CDRH. Performance plans for two of these executive employees—one from CBER and the other from CDRH—explicitly stated that the employees are expected to meet timeliness goals associated with PDUFA or MDUFA.
  - The performance plan for the Director of the Office of Compliance and Biologics Quality in CBER stated that the employee should "Continue to provide timely reviews of applications and supplements, and meetings with industry. Measure: Meet PDUFA and MDUFMA goals for reviews and meetings through July 31, 2012."
  - The performance plan for the Director of the Office of In Vitro Diagnostic Safety and Evaluation in CDRH stated that the employee should, "By September 30, 2012, achieve 90% completion of 510(k)s within 90 days."

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FDA Employee Performance Standards

Timeliness Standards for Nonexecutive CDER Employees

- Employee timeliness is mentioned as one part of the performance plan templates that CDER provided for all 18 nonexecutive employee positions involved in the review of applications. None of the templates explicitly stated that the employees are expected to meet timeliness goals associated with PDUFA. However, two templates referred to FDA guidance that explicitly mentions these timeliness goals.
- For example, the performance plan template for clinical analysts stated that these employees are expected to complete evaluations, “in a timely manner, as determined by the supervisor.”

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FDA Employee Performance Standards

Timeliness Standards for Nonexecutive CBER Employees

- Employee timeliness is mentioned in the performance plan templates CBER provided for all five nonexecutive employee positions involved in the review of applications. Two of these templates explicitly stated that the employees are expected to meet timeliness goals associated with PDUFA or MDUFA.

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FDA Employee Performance Standards

Timeliness Standards for Nonexecutive CBER Employees (cont.)

- For example,
  - The performance plan template for a research regulator stated that this employee should conduct "comprehensive science-based reviews of regulatory submissions for products regulated by CBER," and that these reviews "should comply with milestones specified in PDUFA, MDUFMA, and Center/Office review management procedures."
  - The performance plan template for a nonexecutive manager in CBER stated that the manager should provide direction "in accomplishing Agency/Center/Office Strategic goals and commitments," and that the manager should convey "a sense of urgency" to employees.

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FDA Employee Performance Standards

Timeliness Standards for Nonexecutive CDRH Employees

- Employee timeliness is mentioned in the performance plan templates CDRH provided for all six nonexecutive employee positions involved in the review of applications. Four of these templates explicitly stated that the employees are expected to meet timeliness goals associated with MDUFA.

- Language from the MDUFA goals was included in the templates for some nonexecutive CDRH employees. The pattern in CDRH—with nonexecutive performance plan templates citing MDUFA goals, but the Center Director plan making no reference to the goal—is in contrast to the pattern in CDER, where the Center Director plan mentioned the PDUFA goals but the nonexecutive templates did not.

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FDA Employee Performance Standards

Timeliness Standards for Nonexecutive CDRH Employees (cont.)

- For example,
  - The performance plan template for a premarket reviewer in CDRH's Office of Device Evaluation stated that a fully successful reviewer will complete reviews "within statutory deadlines to meet Office goals and MDUFA goals."
  - The performance plan template for a manager in CDRH's Office of Device Evaluation stated that a fully successful manager "informs and motivates staff to meet established MDUFA goals for assigned documents."

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FDA Employee Performance Standards

Timeliness Standards for Commissioned Corps Officers

- Commissioned Corps officers—who are not required to use performance plans—are assessed based on eight standards.
  - These eight standards are: Leadership; Initiative and Growth; Communication Skills; Interpersonal Skills; Planning and Organization; Professional Competencies; Analysis, Judgment, and Decision-making; and Overall Effectiveness.
  - Supervisors consider officers' specific duties and responsibilities when assessing them based on these eight standards.
- Because all Corps officers are assessed on these eight standards regardless of where they are stationed, the standards do not include timeliness goals related to PDUFA and MDUFA. However, the Planning and Organization standard does include a general mention of timeliness.

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Agency Comments

- To obtain agency comments, we provided a draft of these briefing slides to FDA and discussed the draft with agency officials. FDA provided oral and e-mail comments.
- The agency generally agreed with the information presented in the draft and also provided technical comments, which we incorporated as appropriate.

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