FOOD AND DRUG ADMINISTRATION

Opportunities Exist to Better Address Management Challenges

What GAO Found

Overall, while FDA is aware of its challenges and has taken steps to address them, the agency does not fully use practices for effective strategic planning and management. GAO identified five major management challenges that could affect FDA’s ability to carry out its mission, and while FDA’s 2007 Strategic Action Plan contains strategies to address these challenges, progress has been uneven. Through reviewing reports from GAO, the Institute of Medicine, the Department of Health and Human Services, and the FDA Science Board, GAO determined that FDA’s management challenges include recruiting, retaining, and developing its workforce; modernizing its information systems; coordinating internally and externally; communicating with the public; and keeping up with scientific advances. GAO’s 2009 survey asked FDA managers whether they thought the agency had made progress in addressing its management challenges. A minority of FDA managers responding to the survey reported that the agency was making great progress on meeting most of these challenges—the exception was for public communication. For example, less than one-half of FDA managers reported great progress in addressing workforce issues. GAO also found that FDA lacks an agencywide strategic human capital plan, which reduces the agency’s ability to strategically strengthen its human capital.

FDA’s 48 annual performance measures for fiscal year 2010 are not as useful for decision makers as they could be because they are only partially results-oriented. The measures adhere to some of the key characteristics GAO identified in prior work that can help provide decision makers with useful information on an agency’s results—for example, they are linked to agency goals. However, FDA’s measures do not adhere to other key characteristics because they do not focus on outcomes, address important dimensions of agency performance, identify projected levels of performance for multiyear goals, or fully address identified management challenges.

While FDA has taken steps to align its activities and resources to strategic goals, these efforts in its centers and offices are not clear, making it difficult to connect the agency’s use of resources to the achievement of its goals. FDA has aligned its three main types of activities—pre-market review, production oversight, and post-market surveillance—and uses employee performance plans to link individuals’ activities to its strategic goals. However, only four of eight centers and offices GAO reviewed clearly documented alignment of their activities to FDA’s goals, and only two clearly linked their resources to goals, in part because several centers and offices do not track workload by goals.

What GAO Recommends

GAO recommends that the Commissioner of FDA take several actions to improve FDA’s strategic planning and management, such as developing a strategic human capital plan and working to make the agency’s performance measures more results-oriented. FDA agreed with the recommendations.

View GAO-10-279 or key components. To view the e-supplement online, click on GAO-10-280SP. For more information, contact Lisa Shames at (202) 512-3841 or shamesl@gao.gov, or Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

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