INFORMATION TECHNOLOGY

FDA Needs to Establish Key Plans and Processes for Guiding Systems Modernization Efforts

Why GAO Did This Study

The Food and Drug Administration (FDA) relies heavily on information technology (IT) to carry out its responsibility for ensuring the safety and effectiveness of certain consumer products. Recognizing limitations in its IT capabilities that had been previously identified in studies by FDA and others, the agency has begun various initiatives to modernize its IT systems. GAO was asked to (1) evaluate the agency's overall plans for modernizing its IT systems, including the extent to which the plans address identified limitations or inadequacies in the agency's capabilities, and (2) assess to what extent the agency has put in place key IT management policies and processes to guide the implementation of its modernization projects.

GAO analyzed FDA's plans to determine whether they followed best practices and addressed capability limitations, reviewed key management policies and processes, and interviewed agency officials.

What GAO Recommends

GAO is recommending that FDA expeditiously develop a comprehensive IT strategic plan, give priority to architecture development, and complete key elements of IT human capital planning. In commenting on a draft of this report, FDA agreed with GAO's recommendations and identified actions initiated or planned to address them.

View GAO-09-523 or key components.
For more information, contact Valerie C. Melvin at (202) 512-6304 or melvinv@gao.gov.

What GAO Found

In response to federal law and guidance and urgent mission needs, FDA is pursuing numerous modernization projects (including 16 enterprisewide initiatives), many of which are in early stages. However, FDA does not have a comprehensive IT strategic plan to coordinate and manage these initiatives and projects. Such a plan would describe what the agency seeks to accomplish, identify the strategies it will use to achieve desired results, and provide results-oriented goals and performance measures that permit it to determine whether it is succeeding. FDA has developed two high-level planning documents that include some of these elements, but not all:

- The agency's Strategic Action Plan provides high-level goals and objectives related to modernization of infrastructure and systems, but it does not provide details on IT initiatives, such as milestones and performance measures.
- An IT plan for FDA's user fee program for drugs and biological products focuses on selected projects in greater detail, but these projects are only a subset of the agency's modernization initiatives.

As reflected by its projects and high-level plans, FDA intends to address most of the limitations in its IT systems and infrastructure that had been previously identified. However, successfully overcoming these limitations depends in part on the agency's developing and implementing appropriately detailed plans. A comprehensive IT strategic plan, including results-oriented goals and performance measures, is vital for guiding and coordinating the agency's numerous ongoing modernization projects and activities. Until it develops such a plan, the risk is increased that the agency's IT modernization may not adequately meet the agency's urgent mission needs.

FDA has made mixed progress in establishing important IT management capabilities that are essential in helping ensure a successful modernization. These capabilities include investment management, information security, enterprise architecture development, and human capital management. For example, as part of a move to an enterprisewide approach to IT management, FDA has put policies in place for investment management and project management, and it is making progress in addressing information security. However, significant work remains with regard to enterprise architecture (that is, establishing modernization blueprints describing the organization's operation in terms of business and technology), particularly its "to be" architecture—a blueprint of where it wants to go in the future. Further, the agency is not strategically managing IT human capital—it has not determined its IT skills needs or analyzed gaps between skills on hand and future needs. In both these areas (enterprise architecture and human capital management), the agency's vision for the future, as captured in an IT strategic plan, would be an important asset. Without an effective enterprise architecture and strategic human capital management, FDA has less assurance that it will be able to modernize effectively and will have the appropriate IT staff to effectively implement and support its modernization efforts.

_____ **United States Government Accountability Office**