INFORMATION TECHNOLOGY

FDA Needs to Fully Implement Key Management Practices to Lessen Modernization Risks

Why GAO Did This Study

The Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS), relies heavily on information technology (IT) to carry out its mission of ensuring the safety and effectiveness of regulated consumer products. Specifically, IT systems are critical to FDA's product review, adverse event reporting, and compliance activities. Recognizing limitations in its IT capabilities, the agency has undertaken various initiatives to modernize its systems. GAO was asked to (1) assess FDA's current portfolio of IT systems, including the number of systems in use and under development, and their purpose and costs; (2) assess the status and effectiveness of FDA's efforts to modernize the mission-critical systems that support its regulatory programs; and (3) examine the agency's progress in effectively integrating and sharing data among key systems. To do this, GAO reviewed information on key FDA systems and interviewed agency officials to determine the status of systems and the effectiveness of key IT management practices, as well as data sharing among key systems.

What GAO Recommends

GAO is recommending that FDA develop a comprehensive inventory of its IT systems, develop an integrated master schedule for a major modernization effort, and assess information needs to identify opportunities for greater sharing. In commenting on a draft of this report, HHS neither agreed nor disagreed with the recommendations but stated that FDA has taken actions to address many of the issues in the report.

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What GAO Found

While FDA has taken several important steps toward modernizing its IT environment, much remains to be done. FDA reported spending about $400 million for IT investments in fiscal year 2011; however, the agency currently lacks a comprehensive IT inventory that identifies and provides key information about the systems it uses and is developing. Office of Management and Budget (OMB) and GAO guidance call for federal agencies to maintain such an inventory in order to monitor and manage their IT investments. This inventory should include information on each system, such as costs, functionality or purpose, and status. However, FDA does not have such a comprehensive list of its systems. Instead, the agency points to budget documents required by OMB, which included information on 44 IT investments for fiscal year 2011. The agency also provided a partial list of 21 mission-critical systems and modernization initiatives. Nonetheless, agency officials acknowledged that these documents do not identify all FDA's systems or the complete costs, purpose, or status of each system. Until the agency has a complete and comprehensive inventory, it will lack critical information needed to effectively assess its IT portfolio.

Much work remains on FDA's largest and costliest system modernization effort— the Mission Accomplishments and Regulatory Compliance Services program. This program is estimated to cost about $280 million and is intended to enhance existing applications and develop new systems that provide information for inspections, compliance activities, and laboratory operations. However, much of the planned functionality has not been delivered and its completion is uncertain. Moreover, the program lacks an integrated master schedule identifying all the work activities that need to be performed and their interdependencies. FDA's Chief Information Officer (CIO) stated that the agency is reevaluating the scope of the initiative. As a result, it is uncertain when or if FDA will meet its goals of replacing key legacy systems and providing modernized functionality to support its mission. In addition, FDA has not yet fully implemented key IT management capabilities essential for successful modernization, as previously recommended by GAO. These include developing an actionable IT strategic plan, developing an enterprise architecture to guide its modernization effort, and assessing its IT human capital needs. This is due in part to the fact that FDA's IT management structure has been in flux. Since 2008, the agency has had five CIOs, hampering its ability to plan and effectively implement a long-range IT strategy. While the agency recently hired a CIO, without stable leadership and capabilities, the success of FDA's modernization efforts is in jeopardy.

The agency currently has initiatives under way to improve its data sharing with internal and external partners, including adoption of an enterprisewide standard for formatting data and several projects aimed at enhancing its ability to share data. Effective data sharing is essential to its review and approval process, inspection of imports and manufacturing facilities, and tracking of contaminated products. However, these projects have made mixed progress, and significant work remains for FDA to fully implement standardized data sharing. Further, FDA's Center for Food Safety and Applied Nutrition has not comprehensively assessed information-sharing needs to ensure that its systems and databases are organized for effective information sharing. This is needed to help ensure more efficient access to and sharing of key information supporting its mission.

_____ **United States Government Accountability Office**