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### FDA plans standards, automation for drug submissions

By **Mary Mosquera**  
Published on October 25, 2007

The Food and Drug Administration is trying to increase the number and quality of electronic submissions for drug applications. That is one of the goals of a five-year information technology plan to develop a more integrated, standards-based and automated regulatory e-submission and review environment.

FDA will have a draft by Dec. 31 and a final document by May 30, 2008.

The agency receives more than 100,000 submissions a year, 15 percent of which are submitted electronically, said Tim Stitely, FDA's chief information officer.

"We're seeing an uptake to about 40 percent for larger applications being submitted electronically," he said at a public meeting Oct. 19 on how IT can support the process to review drug applications.

FDA needs a modernized IT infrastructure to better support

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