FDA gives all employees agentic AI tools after 70% take-up of Elsa

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The U.S. Food and Drug Administration today announced the deployment of agentic AI capabilities for all agency employees. Agentic AI capabilities will enable the creation of more complex AI workflows — harnessing various AI models — to assist with multi-step tasks. Agentic AI refers to advanced artificial intelligence systems designed to achieve specific goals by planning, reasoning, and executing multi-step actions. These systems incorporate built-in guidelines — including human oversight —to ensure reliable outcomes. The tool is entirely optional for FDA staff and is used voluntarily. “We are diligently expanding our use of AI to put the best possible tools in the hands of our reviewers, scientists and investigators,” said FDA Commissioner Marty Makary, M.D., M.P.H. “There has never been a better moment in agency history to modernize with tools that can radically improve our ability to accelerate more cures and meaningful treatments.” In May, the agency deployed an LLM-based tool, Elsa, voluntarily used by more than 70% of staff, according to internal agency data. Since that initial deployment, FDA program teams have driven frequent modifications to better integrate Elsa into workflows. Today’s agentic AI deployment will enable FDA staff to further advance the use of AI to assist with more complex tasks, such as meeting management, pre-market reviews, review validation, post-market surveillance, inspections and compliance and administrative functions. As part of the agentic AI deployment, the agency is launching a two-month Agentic AI Challenge for staff to build Agentic AI solutions and demonstrate them at the FDA Scientific Computing Day in January 2026. “FDA's talented reviewers have been creative and proactive in deploying AI capabilities — agentic AI will give them a powerful tool to streamline their work and help them ensure the safety and efficacy of regulated products,” said Chief AI Officer Jeremy Walsh . Built within a high-security GovCloud environment, the models do not train on input data nor any data submitted by regulated industry, safeguarding the sensitive research and data handled by FDA staff. The deployment is another major step in the agency’s multifaceted plan to embed AI more deeply into workflows and achieve unprecedented operational efficiency.

Media: FDA Request for Comment 202-690-6343

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Boilerplate

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, radiation-emitting electronic products, and for regulating tobacco products.