

Comments on FDA's Discussion Paper on GenAI in Health Care Due October 19

Digital Health

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The comment period remains open for the Food and Drug Administration's [discussion paper](#) on regulatory considerations for generative artificial intelligence (GenAI)-enabled medical devices. The paper outlines a potential framework designed to address the unique capabilities and risks associated with GenAI technologies, including a two-axis risk assessment model and a premarket evaluation approach based on "competency assessment." Under this approach, GenAI-enabled devices would be evaluated through a combination of non-clinical benchmarking and clinical confirmation to demonstrate that they perform as intended before reaching patients. The discussion paper also explores risk-based postmarket monitoring strategies and identifies key regulatory considerations for foundation models and increasingly autonomous agentic AI systems. Collectively, the proposals offer an early look at how the FDA may approach oversight of the next generation of AI-enabled medicine.

[Comments are due by October 19, 2026.](#)