

FDA's New Digital Health Guidance Signal Shift for Wellness Devices and CDS

[Digital Health](#)

01.14.26

On January 6, 2026, the Food and Drug Administration (FDA) released updated guidance on Clinical Decision Support Software, as well as General Wellness: Policy for Low Risk Devices, providing clarity to an industry grappling with innovation and regulatory expectations. Both guidance documents contain additional explanation from the FDA on the definitions and applicable regulations which apply to general wellness products and clinical decision support (CDS) software. Read more [here](#).