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INSIGHT

FDA Oversight of General Wellness Products

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General wellness products, and particularly noninvasive, wearable sensing technologies, have proliferated in recent years. These products may be used for a variety of wellness applications, include products like smartwatches and rings, and increasingly include multiple functions to provide data and notifications around fitness and some physiological parameters. In 2016, the 21st Century Cures Act (P.L. 114-255) carved out certain general wellness software functions from the Federal Food, Drug, and Cosmetic Act (FFDCA) definition of device, and in 2019 the Food and Drug Administration (FDA) issued an update to prior guidance explaining FDA's policy of enforcement discretion for low-risk general wellness products. However, since then, technologies advanced and lack of regulatory clarity for these products accelerated, in particular with respect to sensor-based wearables and certain artificial intelligence (AI) applications, such as wellness chatbots or AI-enabled analytics. To partially address this, in 2026 the Food and Drug Administration (FDA) updated its 2019 general wellness guidance to describe how the policy applies to wearables, including when wearables that "use non-invasive sensing (e.g., optical sensing) to estimate, infer, or output physiologic parameters (e.g., blood pressure, oxygen saturation, blood glucose, heart rate variability)" are general wellness products.

General Wellness Guidance (2026)

In its updated 2026 guidance on general wellness products, FDA maintains the factors that define such products (e.g., general wellness intended use, low risk), but clarifies and somewhat expands the scope of products that may qualify. Specifically, FDA adds criteria that must be met by wearables that use noninvasive sensing to estimate, infer, or output certain physiological parameters to be a general wellness product. Like the 2019 guidance, the 2026 guidance outlines the statutory exemption from the device definition for certain general wellness software functions, as well as a policy of enforcement discretion for other software and non-software devices defined by FDA as general wellness products. Specifically, the FFDCA's device definition excludes any software function that is "for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition." The guidance establishes additionally that general wellness products are both software and non-software products with "an intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition."

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In addition to having one of these two general wellness intended uses, a product must be low risk as defined in the guidance to come under its scope. A product is *not* low risk if it is (1) invasive, (2) implanted, or (3) involves "an intervention or technology that may pose risk to the safety of users and other persons if specific regulatory controls are not applied."

The 2026 guidance adds to the 2019 guidance by addressing when products using noninvasive sensing to "estimate, infer, or output physiologic parameters (e.g., blood pressure, oxygen saturation, blood glucose, heart rate variability)" are general wellness products. These products must, as with any general wellness product, have a general wellness intended use and be low risk. In addition, they must not (1) be intended to diagnose, prevent, or treat a disease or condition; (2) be intended as a substitute for an FDA-authorized, cleared, or approved device; (3) include claims, functionality, or outputs that prompt or guide specific clinical action; and (4) include values that mimic those used clinically unless validated. As illustration, the guidance explains that a wearable product that tracks sleep, sleep quality, pulse rate, and blood pressure may be a general wellness product if (1) it is intended to promote general healthy habits and does not imply the product's use in a medical or clinical context; (2) the technology for monitoring the relevant biomarkers is not invasive or implanted, and does not pose a safety risk without specific regulatory controls; and (3) it has validated values for blood pressure.

The guidance provides examples of general wellness products that are not devices, as well as those that are devices but for which the agency is exercising enforcement discretion. **Table 1** illustrates the applicability of the general wellness policy, based on intended use (and meeting low risk criteria).

Table 1. FDA's General Wellness Product Policy

(All products must be low risk)

General Wellness Intended Use	Software Products	Non-Software Products
Maintaining and encouraging a general state of health or a healthy lifestyle, unrelated to diagnosis, cure, prevention, treatment or mitigation of disease.	Excluded from FFDCA definition of device[a]	Enforcement Discretion
Relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions.	Enforcement Discretion	Enforcement Discretion

Source: CRS analysis of FDA, "General Wellness: Policy for Low Risk Devices," January 6, 2026, https://www.fda.gov/media/90652/download.

a. 21 U.S.C. §360j(o)(1)(b).

Issues for Consideration

Although the updated guidance addresses wearable products, it does not specifically address AI-enabled products. Developers and consumers do not always have clarity on if or when AI-enabled products, for example AI-enabled analytics accompanying wearable products, may fall under the general wellness policy. Additionally, questions remain about the wellness policy and generative AI-enabled products. Recently, FDA's Digital Health Advisory Committee met to discuss the regulation of generative AI-enabled digital mental health devices, where questions arose about distinctions between general wellness products, lower-risk devices that may be under a policy of enforcement discretion, and higher-risk devices that are FDA's focus.

The updated guidance, as noted, is somewhat expanded to include, within specific parameters, wearable products with noninvasive sensing technology that infer or estimate certain physiological parameters. Related policies or activities may reflect or amplify the updated guidance. For example, in its TEMPO pilot, FDA plans to select digital health devices to be included in CMS's ACCESS pilot under a policy of enforcement discretion to gather real world data that may inform device risk-benefit profiles; FDA notes these devices may rely on wearable products, both regulated and unregulated.

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