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FDA Opens Aperture for Wearables in Latest General Wellness Guidance

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On January 6, 2026, the US Food and Drug Administration (FDA) issued two revised guidance documents relating to general wellness products (General Wellness Guidance)[1] and clinical decision support software (CDS Software Guidance).[2] As we previewed in our client alert on Technology-Enabled Meaningful Patient Outcomes (TEMPO) and the companion CMS ACCESS program, a key consideration before applying to TEMPO is whether a particular digital health technology is a medical device under the Federal Food, Drug, and Cosmetic Act (FDCA), considering the carve outs to the device definition created by the 21st Century Cures Act and one or more of FDA's enforcement discretion policies interpreting the law. FDA's push to issue these revised guidance documents on the heels of its recent announcement on TEMPO is unsurprising, as greater clarity on FDA's views on the FDCA and its enforcement discretion policies will benefit both industry considering TEMPO and agency staff evaluating submissions to the new program. Importantly, however, in the push to issue these new guidance documents, FDA skipped the notice-and-comment period typically required for such policy announcements and issued the guidance documents as final, rather than draft, providing no opportunity for public comment.

The 2026 General Wellness Guidance supersedes the 2019 guidance that FDA issued interpreting the FDCA in light of the changes to the statute enacted by the 21st Century Cures Act. That law exempted software functions from the definition of a medical device that are intended "for maintaining or encouraging a healthy lifestyle and [are] unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition," among other exemptions. Notably, Congress did not include any language about adopting a risk-based framework to interpret this exemption; rather, this risk-based approach first appeared in FDA's 2019 guidance. In that guidance, FDA explained that it would exercise enforcement discretion for products intended to promote a healthy lifestyle, if such products are intended for only general wellness use (as defined in the guidance) and present a low risk to the safety of users and other persons.

The current General Wellness Guidance retains this two-part framework, though FDA allows for more flexibility and a broader interpretation of the software functions for which FDA will exercise enforcement discretion, reflecting the shift in the agency's thinking about what is considered "low risk." Specifically, FDA announced in the 2026 General Wellness Guidance that its enforcement discretion policy now expressly includes "wearables," which monitor physiological characteristics. Per the guidance, FDA has clarified that noninvasive, nonimplanted products that estimate, infer or output physiological parameters, such as blood pressure, oxygen saturation, blood glucose and heart rate variability, are subject to FDA's enforcement discretion policy, provided that the outputs are only used for wellness, do not pose a risk to safety, do not substitute for FDA-authorized medical devices, do not prompt or guide clinical action or medical management, are not intended for use in the diagnosis, cure, mitigation or treatment of a disease or condition, and do not mimic values used clinically, unless validated (e.g., validation through manufacturer testing and peer-reviewed clinical literature).

Another significant change is FDA's approach to notifications. While the 2019 guidance was silent on notifications (though the FDA sent Warning Letters to companies taking the position that alerts were evidence that a software function was diagnostic),[3] FDA now clarifies that general wellness products **can** include notifications to a user – as long as such notifications are styled as instructions to seek evaluation by a healthcare professional where the software identifies physiological parameters outside the ranges "appropriate for general wellness use." FDA cautions, however, that such notifications may not name a specific disease or condition; characterize the results as abnormal, pathological or diagnostic; include clinical thresholds, diagnoses or treatment recommendations; or function as ongoing alerts or "monitoring intended to manage a disease or condition." If they do, these types of alerts would render the products as medical devices that are not subject to FDA's enforcement discretion policy.

FDA cautions that product labeling must conform with the enforcement discretion policy and provides in the 2026 guidance a list of labeling, advertising, user interfaces and functionalities that trip the "general wellness" line for FDA. These include:

1. References to specific diseases, clinical conditions or diagnostic thresholds.
2. Alerts, alarms or prompts that recommend or require specific clinical action or medical management.
3. Treatment guidance intended to inform or direct medical management.
4. Claims of clinical equivalence, clinical accuracy, medical- or clinical-grade, or substitution for an FDA-authorized, -cleared or -approved medical device.
5. Intended-use statements that explicitly target diagnosis, screening, monitoring or management of a disease or condition.

While this guidance overall appears to move in the right direction to encourage innovation in the health and wellness space, there are some inconsistencies in the current General Wellness Guidance that could lead to confusion across the industry. For example, FDA's guidance (consistent with the previous iteration) emphasizes that general wellness products include those with "intended uses to promote, track, and/or encourage choice(s) which, as part of a healthy lifestyle, may help living well with certain chronic diseases or conditions." Yet, it is unclear how a product intended to "help living well with certain chronic diseases or conditions" could also conform with FDA's statements that the product cannot "make reference to specific diseases or conditions" in its labeling, advertising, user interface or functionality. It is also unclear how products with these intended uses can include notifications without mentioning the diseases or conditions that users are trying to manage with the software. We hope FDA will consider public comment on this newly issued guidance, which will also afford the agency an opportunity to consider – and potentially correct or reconcile – these apparent inconsistencies.

In the wake of this updated guidance document, those in the general wellness industry should reevaluate intended-use statements, labeling, marketing and user interface for software functions, as the new guidance opens the aperture for certain types of general wellness products, especially those developing noninvasive physiological sensing and monitoring. Navigating the line between a heavily regulated medical device and a general wellness product that is subject to FDA's enforcement discretion policy remains a complex task, and careful legal analysis is crucial before bringing a product to market, particularly in light of FDA's latest pronouncement.

Cooley's life sciences and healthcare regulatory team is actively working with numerous clients in this space to think through these and related strategic regulatory questions. We are available to discuss the implications of this guidance for your products and advise on FDA requirements and healthcare compliance more generally. For assistance, please contact the authors listed below.

Notes

1. General Wellness: Policy for Low Risk Devices – Guidance for Industry and Food and Drug Administration Staff.
2. Clinical Decision Support Software – Guidance for Industry and Food and Drug Administration Staff. See Cooley's separate client alert on the update to the CDS Guidance.
3. See, e.g., FDA Warning Letter to Owlet Baby Care, Inc., (October 5, 2021).

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