FDA Closeout Letter Suggests Relaxing Stance On Wearables

By **Rachel Forman, Jocelyn Wiesner and Abeba Habtemariam** (September 8, 2026)

Rachel Forman

Jocelyn Wiesner

Abeba Habtemariam

On June 17, the U.S. Food and Drug Administration closed out its Whoop Inc. warning letter, deciding not to pursue further enforcement action, and giving us our first glimpse of how the FDA will implement its revised enforcement discretion policy on general wellness wearables.

The closeout letter, which expressly invoked an updated policy on general wellness products that the FDA issued in January, suggests that the FDA's position on wearable blood pressure estimates might be softening.

Last year, the FDA issued a warning letter to Whoop asserting that the blood pressure insights, or BPI, feature on the Whoop wearable is a medical device. That letter, many believed, was a sign of increased FDA scrutiny of wellness wearables that estimate physiologic parameters associated with the diagnosis of disease.

But then in January, the FDA released two revised final guidance documents, the 2026 general wellness final guidance and an updated guidance on clinical decision support software functions, which appeared to take a different tack in an effort to promote innovation.[1]

In updating the general wellness final guidance, the FDA expanded the scope of general wellness wearables not subject to FDA oversight as medical devices or for which the FDA intends to exercise enforcement discretion. Indeed, one of the FDA's own illustrative examples of a nonregulated general wellness product bore a striking resemblance to Whoop's BPI feature, suggesting that the FDA's position on wearable blood pressure estimation might be softening subject to certain limitations described in the guidance.[2]

That prediction turned out to be true.[3] While the FDA's closeout letter noted changes Whoop made to BPI and its labeling, it also explained that the FDA "does not intend to enforce the device statutory and regulatory requirements for [WHOOP's] BPI product as modified" consistent with the 2026 general wellness final guidance.

Noting that "FDA issued updates to this guidance on January 6, 2026," the closeout letter further explains that the updated guidance describes a policy where the FDA does not intend to examine low risk general wellness products to determine whether they are devices or, if they are devices, whether they comply with applicable premarket or postmarket requirements.

The FDA's warning letter last year identified four aspects of Whoop's BPI that, in the FDA's view, made the product a regulated medical device.

For example, the FDA found that BPI's marketing implied a causal link between a user's blood pressure measurement and their wellness outcomes, which took BPI outside the scope of the 21st Century Cures Act statutory exemption for nondevice software functions for maintaining or encouraging a healthy lifestyle. The FDA also pointed to specific marketing claims, and BPI's color-coded display as evidence of a diagnostic function.

Significantly, the FDA also took the view that BPI was not eligible for enforcement discretion under the general wellness guidance in place at the time because even if BPI is intended for only general wellness use, it did not present a low risk to the safety of users.

Specifically, the FDA asserted that, because high blood pressure is the most prevalent modifiable risk factor for cardiovascular disease in the U.S., blood pressure estimation is not a low-risk function. The agency also stated that providing the wrong blood pressure can have significant consequences for the user, including delay or even a lack of treatment, which can result in serious impacts to that patient's cardiovascular health and end-organ damage.

Although Whoop publicly defended BPI,[4] it apparently modified the feature in some limited respects in response to the FDA's warning letter.[5] According to public reporting, Whoop moved away from including medical-grade claims and similarly clinical-sounding language in its marketing that the FDA's original warning letter had cited, while maintaining disclaimers that the product is not a medical device.

Under the 2026 general wellness final guidance, the FDA may consider certain products that use noninvasive sensing (e.g. optical sensing) to estimate, infer or output physiologic parameters (e.g. blood pressure, oxygen saturation, blood glucose, heart rate variability) to be general wellness products when such outputs are intended solely for wellness uses, and provided that they:

- "Are non-invasive and non-implanted";
- "Do not involve an intervention or technology that may pose a risk to the safety of users or other persons if specific regulatory controls are not applied";
- "Are not intended for the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition";
- "Are not intended to substitute for an FDA-authorized, cleared, or approved device";
- "Do not include claims, functionality, or outputs that prompt or guide specific clinical action or medical management"; and
- "Do not include values that mimic those used clinically unless validated (e.g., through manufacturer testing or peer-reviewed clinical literature) to reflect those values."

The 2026 general wellness final guidance posits that general wellness products could also display values, ranges, trends, baselines or longitudinal summaries, and put these outputs in terms of sleep, activity, stress, recovery or similar domains. Such products could also deliver a general notification to the user when the user's outputs fall outside of certain ranges, informing the user that an evaluation by a healthcare provide may be helpful.

Notably, it does not appear that Whoop made wholesale changes to its BPI feature or its marketing to remedy everything the FDA called out in its warning letter. The closeout letter, therefore, signals instead that the FDA is embracing a more relaxed stance on certain general wellness wearable functions.

The closeout letter is explicit about the limits of the FDA's decision not to enforce the statutory device requirements. It applies only to Whoop's modified BPI and does not extend to any other Whoop feature or to future modifications of BPI.

Companies should not read the Whoop resolution as a categorical exemption for blood-pressure-adjacent wearable features generally; it is a fact-specific outcome tied to particular product and label changes, assessed against fairly new FDA guidance interpretation; and that guidance's procedural durability will remain an open question as new wearables are developed.

However, the closeout letter is a sign that FDA may not apply the strict oversight over wellness wearables that the Whoop warning letter originally signaled, although the FDA is

likely to continue prioritizing oversight over purported general wellness wearables that pose a risk to consumer health or safety or that compete with FDA-cleared or approved device software functions.

It is worth noting, for example, that shortly after the FDA issued the July 2025 warning letter to Whoop, the agency granted a device marketing authorization to Apple Inc. for a hypertension notification feature for the Apple Watch.

Despite the resolution of the warning letter, Whoop still faces civil lawsuits stemming from it. In the months following issuance of the warning letter, Whoop was named as a defendant to a California class action **alleging** Whoop deceptively marketed its BPI products as capable of providing medical-grade insights and incurred economic injury to the plaintiffs.[6] Since the lawsuit, Rowe v. Whoop Inc., was filed in the U.S. District Court for the Northern District of California on Nov. 18, Whoop has moved away from using "medical-grade" language in its marketing.

Rachel Forman and Jocelyn Wiesner are counsel, and Abeba Habtemariam is a partner, at Arnold & Porter Kaye Scholer LLP.

Arnold & Porter partner Julie du Pont contributed to this article.

[1] Arnold & Porter, FDA "Cuts Red Tape" on Clinical Decision Support Software and Wearable Products for General Wellness (Jan. 21, 2026), https://www.arnoldporter.com/en/perspectives/advisories/2026/01/fda-cuts-red-tape-on-clinical-decision-support-software.

[2] 2026 General Wellness Final Guidance at 9 (illustrative example 7).

[3] FDA, Warning Letter to WHOOP Inc., MARCS-CMS 709755 (July 2025).

[4] See, e.g., https://www.linkedin.com/posts/willahmed_innovation-healthtech-wellness-

activity-7361796998749908992-vRVj/.

[5] See FDA Closeout letter.

[6] Rowe v. WHOOP Inc., Case No. 4:25-cv-9910 (N.D. Cal.).