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Food and Drug Administration Warning Letter to Fitness Wearable Sponsor Signals Increased Agency Focus on General Wellness Products

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Many companies that market fitness trackers and other wellness-related wearables believe their products to be outside the oversight authority of the U.S. Food and Drug Administration (FDA or Agency) because the products fall under a statutory exemption for general wellness software functions or under a related FDA enforcement discretion policy.

Specifically, as amended by the 21st Century Cures Act (Cures Act), the Federal Food, Drug and Cosmetic Act (FDCA) excludes from the "device" definition software functions intended "for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition."

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FDA also has a related enforcement discretion policy in place (General Wellness Policy) that applies to a product that has "(1) an intended use that relates to maintaining or encouraging a general state of health or a healthy activity, or (2) 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 outcomes for the disease or condition."[1]

Activity trackers intended to promote physical fitness can potentially be marketed without falling under FDA's oversight, but certain claims and functionalities can render such wearables as regulated medical devices. For example, the Apple Watch has a mix of both non-device wellness functions and regulated medical device functions that require FDA marketing authorization (e.g., sleep apnea and atrial fibrillation detection features). While there are clear distinctions between a wearable that tracks steps and a wearable that provides patient-specific statistics and analysis on heart arrhythmias or sleep

apnea, other wellness wearable functions fall more in the middle of the spectrum.

Whoop, Inc.'s (Whoop or Company) line of popular fitness tracking bracelets are an example of a wellness wearable with functions that fall in the gray area. Whoop's bracelet monitors certain health metrics for the wearer, including sleep quality, cardiovascular and muscle strain, heart rate, and blood pressure (Whoop wearables).

FDA ISSUES WARNING LETTER TO WHOOP

On July 14, 2025, FDA issued a Warning Letter to Whoop, which alleged that the Company's "Blood Pressure Insights" (BPI) is an adulterated and misbranded medical device being marketed by Whoop without required FDA clearance or approval. As described by Whoop's website, BPI provides the Whoop tracker user with once-per-day systolic and diastolic blood pressure estimations.[2] The Company's website further states that BPI is able to estimate morning systolic and diastolic blood pressure using photoplethysmography (PPG, a technology that uses non-invasive light sensors) pulse waveform throughout sleep, along with heart rate, recovery metrics, and demographic factors.

Notably, WHOOP had previously communicated to the FDA that it believed BPI fell under the Cures Act exemption "for maintaining or encouraging a healthy lifestyle . . . unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition." But FDA disagreed, finding that BPI is a "device" subject to FDA's regulatory authority because it relates to the diagnosis of a disease or condition. In the Warning Letter, FDA outlined its reasons for why BPI is a regulated medical device.

WHOOP'S BPI DOES NOT QUALIFY FOR CURES ACT EXEMPTION

In its Warning Letter, FDA stated that BPI does not qualify for the Cures Act exemption for general wellness software functions because:

- BPI is not intended to "maintain" or "encourage" a healthy lifestyle since the product's marketing implies a causal link between a user's blood pressure measurement and wellness results.

- The Company's marketing claim that "higher blood pressure may be an indicator of poor sleep" presents BPI's intended use as being related to the diagnosis, cure, mitigation, prevention, or treatment of a hypotension or hypertension and therefore ineligible for the Cures Act healthy lifestyle software exemption.

Although the FDA did not list all of the statements on Whoop's website underlying its analysis, there are other Whoop marketing statements which could lead a user to believe Whoop is a diagnostic tool. For example:

- Whoop's website states that one of the objectives of Whoop is to "monitor health," measuring "key vitals like heart rate, blood oxygen, skin temperature, and more, so you can understand your baseline, get alerted when your metrics deviate, and share data with your healthcare team."[3]

- Whoop's podcast on YouTube invites guest speakers, including doctors and researchers, to discuss varying health issues, including sleep quality,[4] menopause,[5] and chronic disease prevention.[6]

These statements and marketing efforts blur the line between Whoop as a "wellness" product and medical device.

WHOOP'S BPI'S COLOR CODING INDICATES A DIAGNOSTIC FUNCTION

FDA further pointed to the Whoop's use of green, yellow, and orange color coding to indicate a target blood pressure range as evidence that BPI has a diagnostic function. Although not stated explicitly in the Warning Letter, FDA implies that the yellow and orange colors are intended to indicate an abnormal blood pressure condition, namely hypotension or hypertension. FDA has made somewhat similar allegations in Warning Letters issued to other companies. For example, in a 2023 Warning Letter to Abiomed Inc., FDA claimed that alarms color coded as red and orange indicated a product was intended to detect a life-threatening condition (although in that case the instructions for use for the product went further, stating that red meant "critical" and orange meant "serious").[7]

WHOOP'S INTENDED BPI USE IS SIMILAR TO OTHER BP MONITORING DEVICES

FDA also stated that although BPI provides a once-daily blood pressure range and midpoint measurement instead of a real-time reading, it is not sufficient to distinguish the product's intended use from other blood

pressure measurement devices regulated by FDA, such as continuous blood pressure monitors and traditional cuff-based blood pressure measurement devices. In FDA's view, its conclusion is "consistent with prior FDA actions, as FDA has reviewed and cleared as a medical device other blood pressure measurement products intended to provide a measurement or estimation of a user's blood pressure without explicit reference to diagnosis of hypo- or hypertension in their labeling or otherwise."

WHOOP'S BPI IS INELIGIBLE FOR ENFORCEMENT DISCRETION

Finally, in its Warning Letter, FDA reasoned that BPI is not eligible for enforcement discretion under FDA's General Wellness Policy because even if it were established that BPI is intended for only general wellness use, BPI does not present a low risk to the safety of users and other persons because:

- Providing blood pressure estimation is not a low-risk function, and that high blood pressure is the most prevalent modifiable risk factor for cardiovascular disease in the United States.

- An erroneously low or high blood pressure reading 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.

WHOOP PUBLICLY DISAGREES WITH FDA'S CHARACTERIZATION OF BPI

On July 15, 2025, the day after the issuance of the warning letter, Whoop publicly responded that it "respectfully disagree[d]" with the FDA's characterization of BPI as a medical device.[8] Whoop explained that BPI "is a wellness feature" because it is "designed to help you understand how your body responds to daily life, not to diagnose or treat any condition," and that "[w]ellness features like this are common in wearable technology, like tracking your respiratory rate or HRV [heart rate variability]." This response sets up a potential clash between FDA and Whoop, as FDA may pursue seizure and injunction against products that are unlawfully marketed in violation of the FDCA, and can seek injunctions, civil money penalties, and in egregious cases, criminal penalties, for marketing or distributing such products – although in most of these cases FDA may be required to ultimately argue its case in court.

FDA ENGAGING IN GREATER OVERSIGHT OVER WELLNESS WEARABLES

It is not necessarily surprising that FDA decided to issue a Warning Letter to Whoop considering FDA's concerns about the risks of erroneous blood pressure readings. And, PPG is a relatively new technology for use in determining blood pressure, which is a technology that FDA may not be comfortable with.[9] Nonetheless, FDA's Warning Letter to Whoop may be indicative of greater FDA oversight over wellness wearables that previously have not been the focus of the Agency's enforcement priorities.

The Whoop Warning Letter is comparable to a Warning Letter FDA issued four years earlier to Owlet Baby Care, Inc. (Owlet) a company that marketed "smart socks" that measured blood oxygen saturation and pulse rate in infants.[10] In that case, FDA did not allege the company made any explicit claims that the products could be used in the cure, mitigation, treatment, or prevention of a disease, but rather that, in context, marketing claims such as "If your baby's readings leave preset 'safe' zones, the Smart Sock will immediately notify you that your baby needs your attention" demonstrated the products were "intended to identify (diagnose) desaturation and bradycardia." In the Owlet Warning Letter, FDA noted that "since 2016, the FDA has corresponded with Owlet that the Owlet Smart Sock meets the definition of a device under the FD&C Act and does not fall under the compliance policy for low-risk products that promote a healthy lifestyle (General Wellness guidance)."[11]

The Warning Letter against Whoop also follows other actions by FDA against products in the ever-growing wearable health products market, such as FDA's issuance in February 2024 of a warning to consumers, patients, caregivers, and health care providers of risks related to using smartwatches or smart rings that claim to measure blood glucose levels without piercing the skin.[12] Such devices claim to be based on various technologies, such as electrochemical or optical technology, but the FDA warning cautioned that no such device had been approved or cleared by FDA.

The Warning Letter to Whoop serves as a caution to companies with wearable technologies to take care to ensure any marketing of such products on their websites or social media without FDA approval or clearance complies with one or more statutory or enforcement discretion-based exemptions, such as one of the exceptions for certain types of software[13] or FDA's General Wellness Guidance. Additionally, companies in this space who are

seeking to market a wearable product as a medical device (e.g., for use in the diagnosis, cure, mitigation, treatment, or prevention of disease) may want to consider early engagement with the Agency, particularly where the product is based on relatively novel or emerging technology.

Notes

1. FDA, Guidance for Industry and Food and Drug Administration Staff, General Wellness: Policy for Low Risk Devices, Sept. 27, 2019, available at https://www.fda.gov/media/90652/download.
2. See WHOOP, WHOOP Delivers Innovative Blood Pressure Insights for a Deeper Look at Your Well-Being, last accessed September 3, 2025, available at https://www.whoop.com/us/en/thelocker/blood-pressure-insights/?srsltid=AfmBOoq7AAjnoPok8INcRzvvrWqw5d7UGysB7s33QsfHV8hhmY2OX_SB.
3. See WHOOP, How WHOOP Works, last accessed Sept. 3, 2025, available at https://www.whoop.com/us/en/how-it-works/.
4. https://www.youtube.com/watch?v=Fid5bVbJ17E&list=PLXYQX9Aox4mrJDV1tYY5X05FU-sWVTGEv&index=3.
5. https://www.youtube.com/watch?v=HqNtCk4vJ-w.
6. https://www.youtube.com/watch?v=iaV4L99Faag&list=PLXYQX9Aox4mrJDV1tYY5X05FU-sWVTGEv&index=17.
7. See FDA Warning Letter to Abiomed Inc., Sept. 18, 2023.
8. See WHOOP, Why WHOOP Stands Behind Blood Pressure Insights, last accessed September 3, 2025, available at https://www.whoop.com/us/en/thelocker/why-whoop-stands-behind-blood-pressure-insights/?srsltid=AfmBOoqdFtQV18FwQ3GjxsvA1TPOpvHf-JtN6Js1hlVXF6mk0KBm-QEQ.
9. See, e.g., Noh SA et al., History and evolution of blood pressure measurement, Clin Hypertens, 30(1):9 (discussing recent developments in use of PPG to measure blood pressure), April 1, 2024.
10. See FDA warning letter to Owlet Baby Care, Inc. (Oct. 5, 2021). Owlet Baby Care, Inc. later secured FDA marketing authorization for several of its "smart sock" infant products.
11. Owlet subsequently secured FDA authorization to market certain infant "smart sock" devices as medical devices.
12. U.S. Food & Drug Administration, Do Not Use Smartwatches or Smart Rings to Measure Blood Glucose Levels: FDA Safety Communication, February 21, 2024, available at https://www.fda.gov/medical-devices/safety-communications/do-not-use-smartwatches-or-smart-rings-measure-blood-glucose-levels-fda-safety-communication.
13. See 21 U.S.C. 360j(o).