

The FDA Opens a Wider Door for Wellness Wearables

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As Americans kick off the new year with resolutions to get fit, sleep better, and take better care of themselves, the FDA has broadened access to the wearable wellness device market to a greater number of products. In a related media interview, FDA Commissioner Marty Makary indicated that the FDA intends to let companies have very clear guidance that if a device is simply providing information, that can be done without FDA regulation.¹ Still the same, however, is the need for marketers to carefully assess their products' and their claims' ability to safely fit within the parameters of the FDA's guidance to avoid scrutiny or potential enforcement.

Which Guidance Did the FDA Update?

As part of a broader effort to reduce regulatory burdens on artificial intelligence and software that provides information, the FDA updated its guidance on [General Wellness: Policy for Low Risk Devices](#), superseding its last update in 2019. Much of the guidance remains intact without change, maintaining the FDA's longstanding post-21st Century Cures Act policy that the Center for Devices and Radiological Health (CDRH) does not intend to examine whether low-risk general wellness products are devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) or require such products to comply with premarket review and post-market regulatory requirements.

The FDA's updated guidance is aligned with the current administration's focus on improving consumer wellness through healthier habits and foods. The updated guidance provides a refreshed list of examples of products that the FDA does not seek to regulate as medical devices (e.g., smart watches that help consumers track sleep, pulse rate, etc.) and helpfully broadens the type of information that can be provided by such devices to include information such as blood pressure and blood glucose levels, so long as the information is intended for general wellness only and not to diagnose, treat, or manage any disease or other condition.

What Is a General Wellness Product Not Regulated by the FDA as a Medical Device?

The FDA defines general wellness products as products:

1. Intended for only general wellness use; and
2. Presenting a low risk to the safety of users and other persons.²

If a product is intended for non-general wellness use or is not low risk, it is not a general wellness product covered by the updated guidance.

Intended for General Wellness Use

For a product to be considered a general wellness product, it can only be intended for general wellness use, meaning an intended use that relates to either:

1. Maintaining or encouraging a general state of health or a healthy activity; or

¹ FDA announces major shift on wearable health tech as AI revolution accelerates, available at: <https://www.foxbusiness.com/video/6387305587112>.

² FDA, [General Wellness: Policy for Low Risk Devices](#) 2 (Jan. 2026).

2. The role of a healthy lifestyle, helping reduce the risk or impact of certain chronic diseases or conditions.³

Sustaining or Improving Functions Associated with General Health

The first category of general wellness intended uses involves claims about sustaining or improving functions associated with general health, without referencing specific diseases or conditions. Specifically, the FDA considers this first category to relate to: (1) weight management, (2) physical fitness, (3) relaxation or stress management, (4) mental acuity, (5) self-esteem (i.e., cosmetic devices that only make claims related to self-esteem), (6) sleep management, or (7) sexual function.⁴

The guidance offers the following examples as claims indicative of an intended use in sustaining or improving functions associated with general health:

- Claims to promote or maintain a healthy weight, encourage healthy eating, or assist with weight loss goals
- Claims to promote relaxation or manage stress
- Claims to improve general mobility or to assist individuals who are mobility impaired in recreational activity
- Claims to improve mental acuity, instruction following, concentration, problem-solving, multitasking, resource management, decision-making, logic, pattern recognition, or eye-hand coordination
- Claims to promote sleep management (i.e., track sleep trends)

Claims that a product can help treat or diagnose a disease or condition fall outside the scope of permitted general wellness claims. This includes, for example, claims that a product will “treat or diagnose obesity,” “treat an eating disorder,” “treat or diagnose autism,” or “treat an anxiety disorder.”⁵

Sustaining or Improving a Healthy Lifestyle to Reduce the Impact of Chronic Conditions

The second category of general wellness claims allows reference to certain chronic diseases and conditions in the following scenarios:

- Intended uses to promote, track, and/or encourage choice(s), which, as part of a healthy lifestyle, may help reduce the risk of certain chronic diseases or conditions
- 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

To make a claim that references a specific chronic disease or condition, the claim that the healthy lifestyle choice (i.e., exercise, healthy eating) may be beneficial in reducing the risk of or otherwise living with the

³ Id. at 3.

⁴ Id.

⁵ Id. at 4.

chronic disease or condition must be generally accepted.⁶ The FDA expects that associations between the healthy lifestyle choice and chronic disease or condition be supported by peer-reviewed scientific publications or official statements made by healthcare professional associations.⁷

Low-Risk General Wellness Products

In addition to being intended only for general wellness use, a product must be low risk for the general wellness policy to apply. Under the guidance, the FDA identifies three questions as a guide to determining whether a product is low risk:⁸

1. Is the product invasive (i.e., penetrate or pierce the skin or mucous membranes of the body)?
2. Is the product implanted?
3. Does the product involve an intervention or technology that may pose a risk to the safety of users and other persons if specific regulatory controls are not applied, such as risks from lasers or radiation exposure?

If the answer to any of the above questions is “YES,” the general wellness product is not low risk, and the guidance is inapplicable. In addition, when assessing whether a product is low risk, the FDA recommends considering whether CDRH actively regulates similar products as the product in question.⁹

General Wellness Products Can Measure Physiologic Parameters Like Blood Pressure

In an apparent departure from a [Warning Letter issued to Whoop, Inc.](#) only six months ago for a product providing blood pressure insights for general wellness purposes, the FDA has now clarified that products that estimate, infer, or output physiologic parameters may be general wellness products. In addition to being intended for general wellness use and being low risk, such products must not:

- Be intended to substitute for an FDA-authorized, cleared, or approved device
- Include claims, functionality, or outputs that prompt or guide specific clinical action or medical management
- Include values that mimic those used clinically unless validated (e.g., by manufacturer testing or peer-reviewed clinical literature) to reflect such values

Additionally, such products’ labeling, advertising, or user interface must not include:

- References to specific diseases, clinical conditions, or diagnostic thresholds
- Alerts, alarms, or prompts recommending or requiring specific clinical action or medical management
- Treatment guidance intended to inform medical decisions
- Claims of clinical equivalence, accuracy, or substitution of an FDA-authorized, cleared, or approved medical device

⁶ Id. at 5.

⁷ FDA, [General Wellness: Policy for Low Risk Devices](#) 5 (Jan. 2026).

⁸ Id.

⁹ Id.

- Intended-use statements explicitly targeting diagnosis, treatment, screening, or monitoring of a disease or condition¹⁰

One caveat is that the updated guidance allows general wellness products to notify its user that evaluation by a medical professional may be advisable when outputs fall outside certain ranges.¹¹ Such notifications cannot identify or name a specific disease or condition, characterize the output, provide clinical thresholds, diagnosis or treatment recommendations, or provide ongoing alerts intended to manage a disease or condition.

Conclusion

Products satisfying FDA's criteria for general wellness products are not expected to comply with premarket review and post-market regulatory requirements for medical devices. Products that are either intended for non-wellness uses or non-low risk may be subject to such requirements.

¹⁰ Id. at 6.

¹¹ Id.