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FDA Issues Final Guidance for General Wellness Devices

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The final guidance confirms FDA's enforcement discretion for many fitness and wellness technologies but raises issues for certain testing services.

On July 29, the ***US Food and Drug Administration (FDA)*** announced the availability of its guidance document, General Wellness: Policy for Low Risk Devices. This is the finalized version of the draft guidance document FDA issued on January 20, 2015. The final document describes FDA's policy of enforcement discretion for devices that are intended for "general wellness" uses and are "low risk," as those terms are defined in the final guidance. The finalization of this guidance document is a welcome step for the ever-expanding fitness/wellness technology industry, as it provides clarity and certainty that many such products, including wearable fitness trackers, weight loss apps, exercise equipment, and sleep management technologies, will be exempt from FDA oversight. However, changes made in the final version may adversely affect some consumer-oriented testing services and products that require blood samples.

Overview

The final guidance exempts from active FDA oversight devices that are intended only for general wellness use and present a low risk to the safety of users and other persons. With regard to the first factor, FDA states that a general wellness product includes those that are intended to (1) maintain or encourage a general state of health or a healthy activity or (2) support a healthy lifestyle to reduce the risk or impact of certain chronic diseases or conditions. The final guidance states that the second type of general wellness claim may only be used "where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition."

In determining whether a product is low risk, FDA identifies three factors to consider:

- Is the product invasive?
- Is the product implanted?
- 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 product does not qualify as low risk.

Notable Changes

Overall, the final guidance is very similar to the draft guidance. Although most changes made from the draft version were minor or stylistic, some were more significant, including the following:

- The final guidance clarifies that statements from healthcare professional organizations (e.g., the American Medical Association) may be used to substantiate claims that healthy lifestyle choice(s) may play an important role in health outcomes.
- The final guidance states that a product must present a low risk to both users and other persons to qualify as low risk.
- With regard to the questions for determining low risk, the final guidance eliminated the two questions on whether the product “raises novel questions of usability” or “raises questions of biocompatibility.” The final guidance also added a question on whether the product is implanted.
- The final guidance added new examples of general wellness claims and low risk devices.

Of the new examples added to the guidance, one in particular may affect the fast-growing market for consumer-oriented testing services—FDA states in Section IV that a product intended to enhance athletic performance by providing suggestions based on lactic acid testing would not be considered low risk if it “uses venipuncture to obtain the blood samples needed for testing.” This example suggests that certain testing products or services that require blood samples using venipuncture would not qualify as low risk under the final guidance and would not be subject to enforcement discretion. It also signals that FDA considers tests for athletic performance to be medical devices.

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