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FDA Finalizes Guidance on Low-Risk Devices

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The ***Food and Drug Administration (FDA)*** issued final guidance on July 29, 2016, called *General Wellness: Policy for Low Risk Devices*. The guidance clarifies the difference between medical devices regulated by the FDA and so-called "general wellness products," which the agency has indicated it will not actively regulate. A central distinction between the two products relates to the nature of the medical claim: medical devices might claim to diagnose or treat a disease or condition, but general wellness products may only claim to reduce risk or improve living well with such a condition.

Key Takeaways:

- The guidance clarifies that the FDA does not intend to actively regulate "general wellness products," defined as low safety risk products intended for general wellness use. The guidance includes a number of helpful examples of products that will be considered "general wellness products" and permissible general wellness claims.
- Oversight of products that are invasive, implanted, or otherwise pose safety risk will not be affected.
- The guidance does not establish legally enforceable responsibilities but instead describes the FDA's "current thinking."
- It is intended to encourage development of general wellness technologies, such as fitness trackers or mobile apps, which can empower individuals to take a more active role in their health.

Specifically, the FDA's Center for Devices and Radiological Health (CDRH) will not examine low-risk general wellness products to determine (1) whether they meet the definition of medical devices under the Federal Food, Drug, and Cosmetic (FD&C) Act; or (2) if they are devices, whether they comply with FDA regulations (*e.g.*, requirements for premarket notification or review, labeling, good manufacturing practices, and adverse event reporting). The FDA cautioned that inclusion as a general wellness product under the policy does not indicate the product is safe or effective for its intended use. The guidance defines "general wellness products" to include those products that meet two criteria. First, they must be intended only for general wellness use; second, they must present a

low safety risk.

- Intended only for general wellness use. This includes claims that encourage general health or healthy activity without making reference to specific diseases or conditions (*e.g.,* claims relating to weight management, relaxation, and mental acuity). It also includes claims that promote, track, or encourage choices that may help reduce the risk of, or living well with, certain diseases or conditions. General wellness claims associating healthy lifestyle choices with certain health outcomes must be generally accepted (*i.e.,* described in peer-reviewed scientific publications or official statements made by health care organizations). General wellness does not include products that claim to diagnose or treat a disease or condition.

- Present a low safety risk. The product must present a low risk to the safety of the user and other persons. To establish risk, the guidance posits a three-question test: (1) is the product invasive; (2) is the product implanted; and (3) does the product involve an intervention or technology that may pose a risk if specific regulatory controls are not applied. To be a low-risk product, the answer to all questions must be 'yes.' Lasers and radiation exposure are provided as examples of products that carry risk without regulatory controls.

The FDA published a draft version of this guidance on January 20, 2015. The final guidance made several updates to the earlier document. First, it clarified that official statements made by health care professional organizations may be included as evidence of a generally accepted wellness claim. Additionally, the three-question test replaces earlier criteria used to assess a product's risk level. It responds to concerns that the draft guidance questions were confusing and difficult to apply consistently. Finally, it specifically references implants as an example of a product that would not be considered low risk.

This guidance is consistent with the FDA's overall regulatory approach towards health IT as outlined in a 2014 report (see our summary here), as well as with the FDA's approach towards oversight of mobile medical applications. It also follows Senate passage in March 2016 of the Medical Electronic Data Technology Enhancement for Consumers' Health (MEDTECH) Act, which would amend the FD&C Act to preclude the FDA from regulating certain products as medical devices, including software for maintaining or encouraging a healthy lifestyle unrelated to medical treatment. The FDA's guidance will help developers of fitness trackers and mobile apps decide how best to market their products—similar to the bill's objective. However, the guidance will do so without changing any requirements under the FD&C Act and instead relies on the agency's enforcement discretion.

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