

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.

Read more about the FDA's guidance update [here](#).