THE FDA EXEMPTS GENERAL WELLNESS DEVICES AND APPS

The FDA released a draft guidance titled “General Wellness: Policy for Low Risk Devices” to exempt common consumer devices from its regulatory oversight. With over 41 new wearable devices launched at this year’s Consumer Electronics Show (CES)[1] there may be a very good reason the FDA is backing away from these products:

> *CDRH does not intend to examine low risk general wellness products to determine whether they are devices within the meaning of the FD&C Act or, if they are devices, whether they comply with the premarket review and post-market regulatory requirements for devices under the FD&C Act…*

The FDA is saying that the majority of general wellness devices do not require its oversight, and that it will not be specifically examining new devices. Manufacturers will be expected to self-report if their devices or mobile medical apps are considered medical devices under the FDA guidelines. This is a welcome development for healthcare marketers because mobile medical applications are considered devices and so they will fall under this draft guidance.

Criteria

There are two overall criteria that a device or app needs to fall into to be considered a “general wellness” product:

1. The product needs to be only used for general wellness. An app that helps diabetics manage their calorie intake would be considered “general wellness,” but one that also tracks glucose values from a device would not. Note that this does not automatically mean that the manufacturer needs to acquire 510(k) certification, just that it’s not automatically exempt.

2. The product presents a very low risk to the user. A heart-rate sensor used for casual exercise would likely fall into the “general wellness” category but a heart-rate sensor used to determine an irregular heartbeat would definitely not fall into the category.

[1] http://www.klick.com/health/news/blog/mhealth/mobile-health-all-over-ces/

Any claims need to be made softly to ensure a device or app remains in the “general wellness” category. Use of the words “may help” should be used rather than “will help.” An example from the guidance document is fairly typical for an app that would fall into the category:

> *Software Product Y tracks your caloric intake and helps you manage a healthy eating plan to maintain a healthy weight and balanced diet. Healthy weight and balanced diet may help living well with high blood pressure and type 2 diabetes.*

To determine if your mobile medical app or device is part of the general wellness exemption, follow our flowchart based on the FDA guidance document:

The claim made by the product needs to be general in nature, not a specific treatment for a specific disease.

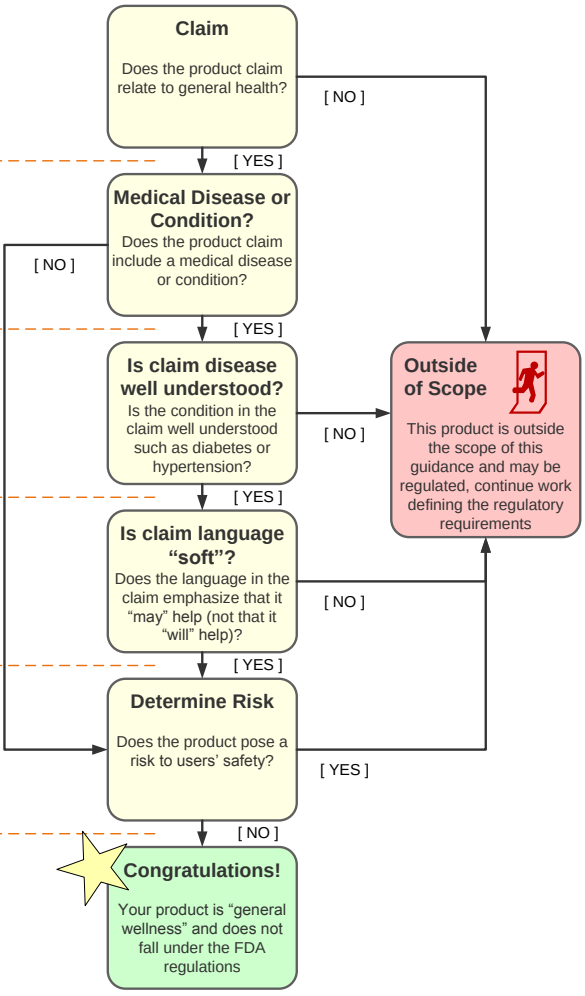
If the claim does not talk about a specific condition you can skip a number of steps.

The disease being discussed needs to be well understood. An app for a rare disease still may not require certification but it is not considered “general wellness.”

Don’t over-promise. The claims can say that the app or device “may” help with a condition but they cannot claim anything concrete.

Regardless of the claims, if there is a safety risk surrounding the product’s usage then the FDA may want it certified.

If your app or device makes it to the end of this flowchart, it is considered “general wellness” and does not need 510(k) certification.



Outcomes

The guidance itself carefully defines all the terms used but healthcare marketers can now build their “general wellness” apps without the threat of FDA 510(k) certification hanging over their heads.

Examples of potential apps provided in the guidance:

- Exercise tracking apps
- Meal and calorie tracking apps
- Relaxation management apps
- Biometrics for exercise, such as heart rate tracking

Healthcare marketers should look at old projects that were rejected in case any of them might now enjoy a level of regulatory certainty that did not exist before.

Questions?

If you have any questions about these developments, reach out to your account representative or contact:

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