On July 29, 2016, the Food and Drug Administration (FDA or the agency) released its final guidance document entitled, General Wellness: Policy for Low Risk Devices (Final General Wellness Guidance). A draft guidance of the same name was published previously on January 20, 2015 (Draft Guidance). The Final General Wellness Guidance reflects the agency’s current thinking on general wellness products. As discussed in further detail below, the Final General Wellness Guidance tracks the Draft Guidance in most respects, with some notable deviations.

General Wellness Product Policy

In summary, consistent with the Draft Guidance, the Final General Wellness Guidance clarifies that FDA does not intend to examine low risk general wellness products to determine whether they are devices under the Federal Food, Drug and Cosmetic Act (FD&C Act), or, if they are devices, to determine whether they comply with the relevant regulatory requirements. Also consistent with the Draft Guidance, a “general wellness product” must be intended only for general wellness use, and it must pose a low risk to the safety of users and other persons. There are two types of intended uses that qualify as general wellness uses:

- an intended use that relates to maintaining or encouraging a general state of health or a healthy activity.
  - This would include claims about sustaining or offering general improvement to functions associated with a general state of health that do not make any reference to diseases or conditions (e.g., claims that focus on weight management, physical fitness, relaxation, enhancing learning capacity).

- an intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition.
  - This would include uses that promote, track, or encourage healthy lifestyle choices that may help reduce the risk of certain chronic diseases or conditions or may help an individual to live well with such a condition. The Final General Wellness Guidance presents heart disease, high blood pressure, type 2 diabetes, anxiety, migraine...
headaches, and skin cancer as examples of chronic conditions where healthy lifestyles are recognized as potentially reducing risk and the impact of the disease.

In addition, a general wellness product must be "low risk," which is determined by evaluating the following product characteristics:

- The product is not invasive;
- The product is not implanted;
- The product does not 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 laser or radiation exposure.

In addition, the Final General Wellness Guidance still provides a general wellness product decision algorithm (General Wellness Decision Algorithm) to help stakeholders analyze whether their product falls under the policy.

**Key Changes According to FDA**

In its public announcement of the Final General Wellness Guidance, FDA noted the following "key changes" from the draft guidance:

- Clarified that CDRH's general wellness policy does not apply to devices that present risks to users' or other persons' safety.
- Clarified that FDA will continue to focus oversight on devices that do not meet the policy's definition of "low risk," as outlined above.

Of the key changes noted by FDA, the change to the definition of "low risk" is more significant. Specifically, FDA removed the requirement that a general wellness product not raise novel questions of usability, or new questions of biocompatibility, but added consideration of whether the product is implantable. The three criteria included in the Final General Wellness Guidance were otherwise captured in the prior "low risk" definition found in the Draft Guidance. Moreover, as indicated above, the agency clarified that general wellness products may not pose risks to users' or other persons' safety. The Final General Wellness Guidance goes on to clarify that simply being classified as a class I device does not necessarily mean that a device is "low risk" under the Final General Wellness Guidance.

**Other Notable Changes**

In addition to the key changes noted by FDA, there are other important differences between the Draft Guidance and Final General Wellness Guidance.

Most notably, the Agency modified the list of claims that may be acceptable for general wellness products. For example, with respect to claims regarding "maintaining or encouraging a general
state of health" FDA made several modifications:

- Claims regarding enhancement of learning capacity were added;
- Claims regarding the enhancement of cardiac function were eliminated from the list of examples; and
- FDA clarified that claims to treat anxiety disorders are not acceptable under this category (i.e., prohibition was altered from claims to treat anxiety to claims to treat anxiety disorders).

Further, with respect to disease specific claims, the Final Guidance, like the Draft Guidance, explains that the association between the healthy lifestyle choice and the health outcomes for a specific disease or condition must be generally accepted. In the Draft Guidance, FDA noted that such an association would typically be described in peer-reviewed scientific publications, leaving open the possibility that the association could be established through other means. In its Final General Wellness Guidance, FDA clarifies that such associations are described in peer-review scientific publications or official statements made by healthcare professional organizations. This change clarifies both that an official statement from a healthcare organization is an acceptable means to establish the association, and suggests that the association is to be established using one of those two sources.

FDA added a new example of an appropriate disease-related claim: mobile app that reminds users to keep exposed skin out of direct sunlight when the UV index is high, which as part of a healthy lifestyle, may help reduce the risk of skin cancer. FDA also added two examples of chronic diseases that would be acceptable to reference under this category: migraine headaches and anxiety.

In addition, FDA added the following to its list of devices that are not "low risk": neurostimulation devices and devices that require a venipuncture.

Interestingly, in the General Wellness Decision Algorithm, FDA altered the possible conclusions such that the most definitive conclusion one may draw is that "the product is likely a general wellness product within the scope of this guidance, but the factors and examples in the guidance should be reviewed to confirm the status of the product." (emphasis added) Under the Draft Guidance, the General Wellness Decision Algorithm allowed stakeholders to conclude that a product was a "general wellness product".

**Key Takeaways**

The Final General Wellness Guidance reflects the same purpose, and largely the same policy structure, as was announced in the preceding Draft Guidance. As with the Draft Guidance, the final general wellness policy has implications for a broad range of device types, but seems to be specifically geared toward the mobile health space. This is evident from the agency's decision to
include four new examples for disease-related general wellness claims, all of which pertained to software devices. The Final General Wellness Guidance also remains consistent with FDA's prior Mobile Medical Apps guidance as it relates to software products intended for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions related to developing or maintaining general fitness, health or wellness. As noted in Hogan Lovells' prior discussion of the Draft Guidance, even if an app exceeds the scope of a general wellness product, it may still fall into the "enforcement discretion" bucket of the MMA Guidance.

Other key takeaways include:

- FDA has modified its definition of "low risk" under the general wellness product policy, and clarified that class I devices are not necessarily "low risk" for purposes of the policy;
- FDA provided three new examples of chronic diseases that could be referenced in a disease-related general wellness claim: migraines, anxiety, and skin cancer;
- When claiming that healthy lifestyle choices may play an important role in health outcomes for a chronic disease, that association must be generally accepted. FDA has clarified that such generally accepted associations are described in peer-review scientific publications or official statements made by healthcare professional organizations.

1 FDA Releases Two New Draft Guidances Aimed at Mobile Health

2 FDA includes a definition for “healthcare professional organization” in footnote 6 of the Final General Wellness Guidance.

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