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FDA Finalizes General Wellness Guidance

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Last week FDA finalized a guidance document entitled "General Wellness: Policy for Low Risk Devices" in which the agency sets forth an approach to not regulate "general wellness products." This guidance document is important to the rapidly growing market for wellness products, which includes such things as activity trackers, smart watches, mobile apps, and other products intended to help monitor and improve consumers' physical fitness, nutrition, or other similar goals. FDA previously published a draft guidance in January 2015 on the same topic, which we blogged about here. This post highlights key differences between FDA's draft and final guidance.

The final guidance adopts the same general approach as the draft guidance – namely, that FDA will not regulate low-risk general wellness products as medical devices, so long as such products meet the definitions and other conditions set forth in the guidance. While adopting the same basic approach, the final guidance provides a few changes from the draft. These changes include the following:

- **Definition of "general wellness products."** The final guidance defines "general wellness products" as products that "(1) are intended for only general wellness use . . . and (2) present a low risk to the safety of users and other persons." This definition reflects a slight change from the draft guidance, which referred to general wellness products as presenting a "very low risk," and clarifies that a product's safety should be assessed with respect not only to the user but also to "other persons."

- **Intended uses for general wellness products.** The final guidance identifies two categories of general wellness intended uses—

1. Products that make 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."

2. Products that make claims about "sustaining or offering general improvement to functions associated with a general state of health while making reference to diseases or conditions." This second category includes products that are intended to promote, track, and/or encourage choices, which, as part of a healthy lifestyle, either (i) may help reduce the risk of certain chronic diseases or

conditions, or (ii) may help living well with certain chronic diseases or conditions.

These two categories are largely the same as in the draft guidance, although the final guidance added the phrase “sustaining or offering general improvement to functions associated with a general state of health while making reference to diseases or conditions” for the second category. This new language does not appear to be a substantive change, but tracks more closely with FDA’s description of the first category.

- **New example of general wellness product.** Like the draft guidance, the final guidance provides a number of “illustrative examples” of low-risk general wellness products. The final guidance adds a new example, describing a “mobile application 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.” The final guidance explains that this claim “relates to tracking preventive measures” that, “as part of a healthy lifestyle, may help reduce the risk of a medical condition.” FDA also notes in its analysis of this example that the technology used to remind the user to keep exposed skin out of direct sunlight would not pose an independent risk to the user’s safety—or to the safety of “other persons”—absent the application of specific regulatory controls.

- **Flow Chart.** The last section of the final guidance sets out questions that can be used as a flow chart to help determine whether a general wellness product falls within the scope of the guidance. The questions in the final guidance are substantively similar to the draft guidance, although some of the wording has changed. The revised questions are as follows:

1. Does the product have an intended use that relates to maintaining or encouraging a general state of health or a healthy activity?

2. Does the product have an intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions? This question can be further broken down into the following:

– Does the product have an intended use that relates to sustaining or offering general improvement to functions associated with a general state of health while making reference to 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?

– Is the relation between healthy lifestyle and disease specifically expressed as “may help to reduce the risk of” or “may help living well with” a chronic disease or condition?

3. Is the product low risk?

FDA will hold a webinar to discuss the final guidance on September 1.

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