Consumer demand for products that maintain and improve their health and wellness has grown steadily during the past decade. Notably, this is reflected in marketing reports talking about the category’s size in terms hundreds of billions of dollars. Against this backdrop, companies have developed and marketed products that seek to meet the consumer’s desires. These products however enter a hazy regulatory environment as some general wellness products are regulated by the Food and Drug Administration (FDA) as a medical device – and some are not.

It is essential for a company to understanding how the FDA will view its regulatory authority over the product prior to launching it. A company that simply assumes its product is beyond the FDA’s authority may find its supply-chain suddenly stopped by the FDA while being subject to an enforcement action, like an import refusal or import alert, or a warning letter. Or a company may wrongly assume that the product is regulated by the FDA, and unnecessarily subject itself to avoidable regulatory burdens, which include user fees. In either situation, a company must conduct its regulatory due diligence early in the design phase for the product to be successful.

**FDA's Regulation of Medical Devices**

The FDA regulates medical devices according to the Food, Drug, and Cosmetic Act (FDCA). This law defines a device as a product that is intended to diagnose, cure, mitigate, treat, or prevent disease, or intended to affect the structure or function of the body, which “does not achieve its primary intended use through chemical action within or on the body of man,” and “which is not dependent upon being metabolized for the achievement of its primary intended purposes.”

If the definition were taken literally, then the FDA would regulate countless products. For example, hiking boots would be a device because they offer support for the feet and ankles, thereby affecting the function of the body. Likewise, a coat and gloves would be device too as they keep the body warm, thereby affecting the function of the body. However, the FDA does not consider either product a medical device. Furthermore, many types of exercise equipment, which can affect the body by building muscles or losing weight, are not medical devices either.

Historically, the FDA made regulatory classification decision on case-by-case basis. This was a time-consuming process, and it provided little clarity or predictability. Against this backdrop, the FDA issued a draft guidance, and then final guidance about “Low-Risk General Wellness Products.”

**Defining ‘Low-Risk General Wellness Products’**
In its guidance from July 2016, the FDA indicated that it would “not regulate [as a medical device] low-risk products that promote a healthy lifestyle (general wellness products).” For a product to fit within this classification, it must satisfy two conditions: 1) it is “intended for only general wellness use” (emphasis in the original); and 2) “presents a low risk to the safety of users and other persons.”

When defining “general wellness” intended use, the FDA established two subcategories. First, general wellness is a product intended to maintain or encourage a “general state of health or of healthy activity.” This subcategory includes claims about weight management, physical fitness, relaxation or stress management, mental acuity, self-esteem, sleep management, or sexual function.

Second, general wellness is a product that “relate[s] to the role of healthy lifestyle, helping 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.” Unlike the other, this subcategory does refer to a disease or condition, but this reference is limited. A product under this subcategory can be intended, for example, to promote physical activity as part of a healthy lifestyle, which may help reduce the risk of high blood pressure. However, the same product cannot claim to treat or cure high blood pressure.

Beyond exclusively having a general wellness intended use, the product must also be “low risk.” In some ways this analysis is more complicated, as the FDA provided minimal guidance as to this definition. However, it did provide examples and three questions to highlight what is not “low risk”: 1) invasive products; 2) implants; and 3) a product that involves “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 lasers or radiation exposure.”

Against this backdrop, the FDA provided several examples about what constitutes a low-risk general wellness product. These include: 1) a product that monitors pulse rate during exercise or hiking; and 2) a product that mechanically exfoliates the skin to make it smoother and softer, but does not penetrate or pierce the skin.

**Practical Implications for General Wellness Products**

As noted, if a product meets the definition of low-risk general wellness product, the FDA will not regulate it as a medical device. This means that the product and the associated entities do not need to comply with: facility registration and product listing; FDA labeling requirements; quality systems regulations; medical device reporting; 510(k) premarket notification; and other FDA requirements.

While the FDA indicated that it would not regulate low-risk general wellness products, the agency will continue to monitor these products to verify that they satisfy the definition. If the product in question falls outside of the definition, the FDA will regulate it as a medical device and subject it to all of the required regulations. This can result in, at best, delays in the supply chain. At worst, it could result in a complete stop to the supply chain and FDA enforcement actions like an import refusal or import alert, or a warning letter.
Thus, not only does a company need to conduct this analysis whether the product is excluded from FDA regulation, it needs to be prepared to defend its conclusion to the FDA. We have witnessed the FDA, especially in the import area, question whether a product is in fact a “general wellness product” and require a company to defend the product’s status.

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