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Food, Drug & Device Law Alert - FDA Issues Draft Guidance On Policy For Low-Risk Devices For General Wellness

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The Food and Drug Administration (FDA) recently issued a draft guidance document titled, “General Wellness: Policy for Low Risk Devices,” to set forth its compliance policy for low-risk devices that seek to promote a healthy lifestyle, which it labels “general wellness products.” In welcome news, FDA states that it “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 and implementing regulations.” The device requirements from which such products will essentially be exempt include registration and listing, premarket notification, labeling, good manufacturing practices and Medical Device Reporting.

The draft guidance “defines general wellness products as products that (1) are intended for only general wellness use, as defined in this guidance, and (2) present a very low risk to users’ safety.” As examples of general wellness products, the draft guidance cites exercise equipment, audio recordings, video games, software programs, and other products that are commonly, though not exclusively, available from retail establishments (including online retailers and distributors that offer software to be directly downloaded), assuming the two criteria above are met.

The draft guidance identifies two categories of intended use for “general wellness” products: “(1) an intended use that relates to a maintaining or encouraging a general state of health or a healthy activity, or (2) an intended use claim that associates 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).” The draft guidance is explicit that it does not apply to a device if its intended uses are not limited to these categories.

For the first category, examples of general wellness claims relate to:

- weight management,
- physical fitness, including products intended for recreational use,
- relaxation or stress management,
- mental acuity,
- self-esteem (e.g., devices with a cosmetic function that make claims related only to self-esteem),

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- sleep management, or
- sexual function.

The draft guidance gives more specific examples of claims that *do* and *do not* fall into this category. For the second category, there are two subcategories of general wellness claims:

1. intended uses to promote, track, and/or encourage choice(s), which, as part of a healthy lifestyle, **may help to reduce the risk of** certain chronic diseases or conditions; and
2. intended uses to promote, track, and/or encourage choice(s) which, as part of a healthy lifestyle, **may help living well with** certain chronic diseases or conditions (FDA's emphasis).

Again, the draft guidance gives more specific examples of such claims. To determine whether a device is low risk, FDA will consider whether or not the product:

1. is invasive;
2. involves an intervention or technology that may pose a risk to a user's safety if device controls are not applied, such as risks from lasers, radiation exposure, or implants;
3. raises novel questions of usability; or
4. raises questions of biocompatibility.

If the answer to even one of these questions is yes, the device is not a low risk general wellness product and is not covered by the draft guidance. The draft offers several examples of low-risk devices.

A copy of the draft guidance can be found here.

For more information, please contact the Barnes & Thornburg LLP attorney with whom you work or one of the following attorneys in the firm's Food, Drug & Device Group: Lynn Tyler at (317) 231-7392 or lynn.tyler@btlaw.com; Hae Park-Suk at (202) 408-6919 or hae.park.suk@btlaw.com.

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