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ALERTS

Food, Drug And Device Law - FDA Finalizes Guidance On General Wellness Devices, Will Not Regulate

August 12, 2016 | Atlanta | Chicago | Columbus | Dallas | Delaware | Elkhart | Fort Wayne | Grand Rapids | Indianapolis | Los Angeles | Minneapolis | South Bend

The FDA recently issued a final guidance titled “General Wellness: Policy for Low Risk Devices.” The guidance sets forth FDA’s compliance policy for low-risk devices that seek to promote a healthy lifestyle, which it labels “general wellness products.” As announced in the draft version, FDA confirms 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 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 final 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 guidance identifies two categories of intended use for “general wellness” products: “(1) sustaining or offering general improvement to functions associated with a general state of health that **do not make any reference to diseases or conditions**”; or (2) sustaining or offering general improvement to functions associated with a general state of health while **making reference to diseases or conditions**” (FDA’s emphasis).

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
- sexual function

The 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 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
4. raises questions of biocompatibility

If the device meets even one of these criteria, it is not a low-risk general wellness product and is not covered by the guidance. The guidance offers several examples of low-risk devices, including some in the final guidance that were not in the draft version.

A copy of the final 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; or Alicia Raines Barrs at (317) 231-7398 or alicia.rainesbarrs@btlaw.com.

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