FDA Issues Draft Guidance on General Wellness Products

Written by Colin J. Zick, Paul T. Kim

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On January 16, 2015, the Food and Drug Administration (FDA) issued a draft guidance document titled "General Wellness: Policy for Low Risk Devices."[1] The draft guidance carves out a category of products, deemed "general wellness products," from regulation by FDA under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The carve-out applies to products that:

1. Are intended for only general wellness use (based on intended use and claims made), and
2. Present a very low risk to users' safety.

While FDA previously indicated that it would not regulate general wellness products, it has not defined this category of products until now. The draft guidance provides a definition that is tied to the intended use of the device, and permits manufacturers to make two types of disease-related claims where there is a "well understood" association between a healthy lifestyle choice and a chronic disease or medical condition.

Although the draft guidance does not establish legally enforceable responsibilities, it provides needed clarification and details for developers of health products, by confirming that many wellness products, including software gadgets and apps, would not be regulated by FDA as devices.

Background

The draft guidance emerged from FDA's ongoing development of a regulatory framework for the regulation of software. FDA has periodically stated that it does not intend to regulate general health and wellness devices. Most recently, FDA reiterated that view in a 2013 guidance titled "Mobile Medical Applications," noting that it would not enforce regulatory requirements for "mobile apps that are intended for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions related to developing or maintaining general fitness, health or wellness…"

In April 2014, the Health IT Committee FDASIA Workgroup, which included representatives from FDA, the Office of the National Coordinator for Health Information Technology, the Federal Communications Commission, and private industry stakeholders, requested that FDA provide greater clarity related to several aspects of medical device regulation involving health IT, including:

1. The distinction between wellness and disease-related claims;
2. Medical device accessories;
3. Medical device clinical decision support software;
4. Medical device software modules; and
5. Mobile medical apps.

The draft guidance on general wellness products appears to be FDA's response to the first item on the Workgroup's list.[2] In the context of the FDASIA Health IT report, the draft guidance on general wellness products identifies the types of wellness products that would be exempt from regulatory requirements under an enforcement discretion approach.

Summary of the Draft Guidance

Under the draft guidance, FDA would not examine low risk general wellness products to determine whether they are devices within the statutory meaning of the term, or if they are devices, whether they comply with FDA's regulatory requirements for devices. The draft guidance defines general wellness products as products that:

1. Are intended for only general wellness use (as defined in the draft guidance), and
2. Present a very low risk to users' safety.

The first part of the definition, concerning intended use, encompasses products for which the intended use and claims refer to sustaining or offering general improvement to conditions and functions associated with a general state of health, such as weight management, physical fitness, relaxation or stress management, mental acuity, self-esteem, sleep management, or sexual function. The definition also includes products for which the intended use claim associates the role of healthy life style 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. Disease claims are appropriate where the intended use of the device may promote, track, and/or encourage choice(s), which, as part of a healthy lifestyle, **may help to reduce the risk of**, or **may help living well with**, certain chronic diseases or conditions. The claims for the device must use this specific language to fall within the scope of the guidance. The link between the healthy lifestyle choice and health outcomes must be generally accepted through peer-reviewed scientific publications.

In assessing whether a device is low risk for the purposes of the draft guidance, FDA suggested that device manufacturers consider whether FDA actively regulates products of the same type as the product in question. FDA outlined four characteristics that indicate inherent risks to users' safety, including where 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

Under the draft guidance, if a device fits within any of these categories, it would not be a general wellness product, and would not be covered by the guidance.

Conclusion

FDA's draft guidance provides more clarity with regard to a safe harbor from regulatory requirements for a variety of wellness devices. Manufacturers and other stakeholders are encouraged to comment on the draft to identify areas of agreement and disagreement, and to request for additional clarification. For example, stakeholders may suggest additions to FDA's list of categories of health claims or request additional categories of low-risk devices. Comments are due on April 20, 2015.

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1. Available here.↩

2. Concurrently with the guidance on general wellness products, FDA issued a draft guidance titled "Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types", addressing the second item on the list as well.↩

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