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ALERT

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FDA Issues Draft Guidances Aimed at Reducing Oversight of Low Risk General Wellness Products and Medical Device Accessories

On Jan. 20, 2015, the U.S. Food & Drug Administration (FDA) issued two anticipated draft guidance documents proposing reduced FDA oversight of two types of products: low risk general wellness products and medical device accessories. The guidances are intended to provide clarity to industry and FDA staff regarding the Center for Devices and Radiological Health's (CDRH's) compliance policy for low risk products that promote a healthy lifestyle, rather than treat or diagnose, and for accessories to regulated medical devices. The FDA is soliciting comments on this guidance and it is unclear when this will be considered final or what the enforcement of these devices will entail prior to completion of the final guidance.

General Wellness Products

The FDA's draft guidance regarding general wellness products provides that the Agency will not examine such products to determine whether they are "devices" within the meaning of the Federal Food, Drug, and Cosmetic (FD&C) Act or, if so, whether they comply with statutory and regulatory requirements applicable to such devices, such as registration, premarket review, labeling, Quality System regulations, and/or adverse event reporting. FDA defines "general wellness products" as products that (1) are intended for only general wellness use, as defined by the guidance, and (2) present a very low risk to users' safety.

The guidance specifies that a general wellness product must fall within one of two categories. It either:

1) has an intended use that relates to maintaining or encouraging a general state of health or a healthy activity (i.e., makes no reference to disease or medical conditions); or

2) has an intended use claim that associates a healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions (where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition.)

If the intended use goes beyond these parameters, then the guidance does not apply.

The guidance includes contrasting examples of products and product claims that do and do not fall within category (1), non-disease related general wellness claims. For example, the guidance would apply to a product that claims to encourage physical fitness and assist with weight management, but it would not apply to a product that claims to treat obesity. Similarly, the guidance applies to a product that promotes relaxation or encourages stress reduction, but not one that treats anxiety. Likewise it would apply to a product that claims to enhance or improve sexual performance, but not one that claims to treat erectile dysfunction.

As to category (2), disease related general wellness claims, products that promote, track or encourage choices that may reduce the risk of certain conditions or which "may help living well with" certain conditions would fall within this category. Under category (2), the connection between the healthy lifestyle and the risk reduction must be well-understood and generally-accepted, such as the connection between physical activity and reducing the risk of high blood pressure or managing caloric intake and "living well with" type 2 diabetes.

The guidance expressly states it does not extend to products that present inherent safety risks. In determining whether a product presents inherent safety risks, one should look at whether the product is invasive, requires the application of device controls to safely apply the technology or intervention, raises novel questions of usability, or raises questions of biocompatibility. For example, radiation emitting devices such as tanning beds, implants, laser devices designed to rejuvenate the skin, and devices that are already actively regulated by CDRH would thus be excluded from the guidance. In contrast, the following examples would be considered low risk general wellness products and fall within the guidance: mobile applications ("apps") or devices that monitor and record daily workout activities or pulse rate, record food consumption, or play stress-reducing sounds or music. Finally, the draft guidance also includes an algorithm to help manufacturers determine whether a product qualifies as a general wellness product.

This guidance is important to manufacturers of personal care, lifestyle and fitness products, as well as to developers of the ubiquitous fitness apps and trackers. Companies in these markets should review their labeling and marketing materials to determine if any adjustments should be made to their product claims or descriptions, since the inclusion of a single, innocuous word such as "obesity" or "anxiety" could have a significant impact as to the level of FDA regulation under this guidance. In addition, it is worth noting that even though certain products may be effectively excluded from FDA oversight, in some cases they may remain subject to Consumer Product Safety Commission (CPSC) standards, regulations and reporting requirements.

Medical Device Accessories

The FDA is recommending a new policy governing the classification pathway and regulation of medical device accessories, including the utilization of a *de novo* classification process under Section 513(f)(2) of the FD&C Act for new types of accessories. This provision provides a pathway to Class I or Class II classification for accessories of a new type without the need to show substantial equivalence to a

predicate device. In doing so, the Agency is acknowledging that many accessories may have a lower risk profile than their parent device and therefore less review and control is warranted.

The FDA's draft guidance regarding **medical device accessories** provides that accessories may be classified in a lower risk class than their parent products, and therefore subject to lower levels of regulation, if certain criteria are met. This is a significant change in policy, because historically the FDA has included device accessories within the same classification as their parent device. Accessory types that have previously been classified or approved through the Premarket Approval (PMA) process will not be reviewed through the *de novo* process, though manufacturers may seek reclassification or exemption from reporting requirements under existing regulations.

The guidance sets forth a two-step inquiry for classification purposes:

1) Is the article an accessory?

2) What is the risk of the accessory when used as intended and what level of regulatory controls are necessary to provide a reasonable assurance of its safety and effectiveness?

The guidance defines "accessory" as a "device that is intended to support, supplement, and/or augment the performance of one or more parent devices" as indicated by its labeling, promotional materials or other evidence. General platforms, such as mobile phones and ordinary computer monitors do not meet this definition. Examples of accessories provided in the guidance include an infusion pump stand that "supports" the performance of the infusion pump, a new balloon catheter that "supplements" the performance of an approved heart valve by allowing it to be inserted into smaller arteries, and surgical tools that "augment" an implantable nerve stimulator by facilitating successful placement.

FDA will evaluate the risks imposed by the accessory's impact on the parent device and any unique risks of the accessory independent of its parent device. If the accessory is determined to be a low risk device, FDA may regulate the accessory as Class I or Class II, even if its parent was a Class III device.

Accordingly, if these recommendations are adopted, manufacturers will be encouraged to utilize the *de novo* classification process under Section 513(f)(2) for all new types of accessories. The guidance provides an Appendix setting forth the exact process and timeline for an accessory *de novo* classification request.

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