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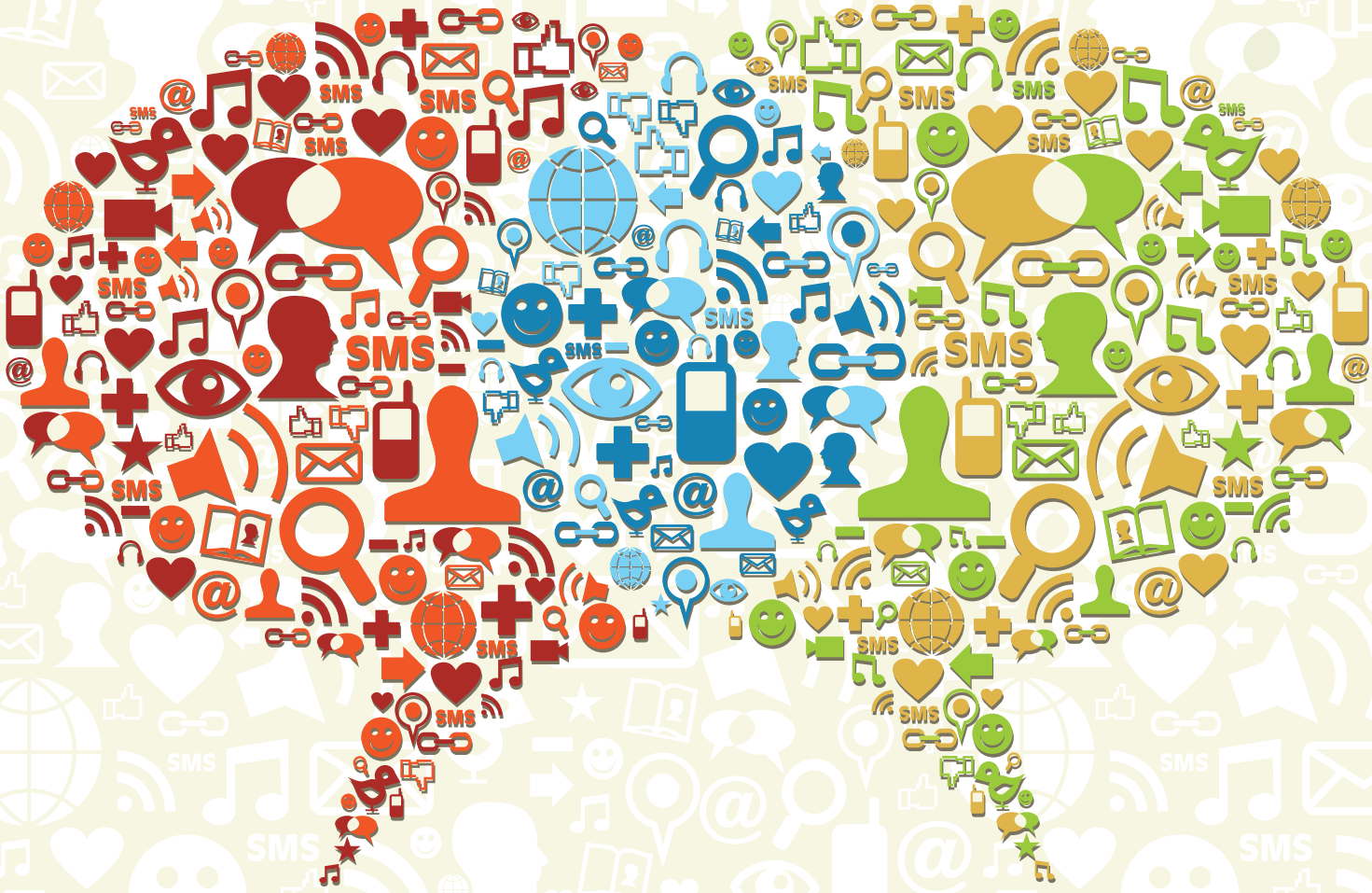

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Low Risk General Wellness Devices

FDA Finalizes Guidance and Further Illuminates Its Policy of Enforcement Discretion

by Mark Mansour, Christopher Mikson, and Emily Strunk

On July 29, 2016, FDA finalized its guidance document *General Wellness: Policy for Low Risk Devices*.[1] The final guidance preserves the overall spirit and function of the draft guidance, issued in January 2015, with a few telling changes that will give wellness product makers additional clarity on the kinds of products that fall within FDA's policy of enforcement discretion for general wellness devices. Perhaps more importantly, the guidance is instructive on how to craft product claims to ensure that products do not overreach the scope of general wellness and land the product and its manufacturer in a more regulated space.

The Federal Food, Drug, and Cosmetic Act, defines a medical device as an "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is …intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease … or intended to affect the structure or any function of the body ..."[2] Under this definition, the mere mention of a disease or condition in a product description triggered, at a minimum, a full analysis as to whether the product would be considered a medical device. In most cases, it would be difficult to find a circumstance where it was not at least arguable that the product was a medical device and subject to regulation as such. There was also considerable uncertainty around products that were promoted for more general health issues. It seemed at least possible that FDA would construe facilitating healthy practices, such as healthy sleep habits or weight loss, as mitigating or treating the disease-or-condition counterpart, such as insomnia or obesity.

FDA's finalized policy comes as a welcome reprieve from unnecessary and ambiguous regulation in a world that is increasingly focused on healthy lifestyles and the latest gadgets or apps that can help facilitate those lifestyles.

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A Framework of non-Regulation for General Wellness Devices

As an initial matter, FDA confirms that it does not intend to even analyze general wellness products to determine if they meet the definition of a medical device. For products that are medical devices, FDA will not evaluate whether the product complies with the premarket review and post-market regulatory requirements for medical devices.

Although this policy is not specific to mobile medical applications or medical device software, many of the examples in the guidance document address software and apps, reflecting an industry with a heavy focus on technology. It is also worth noting that a product that does not meet the criteria for a general wellness device under this policy may still be subject to enforcement discretion under FDA's *Mobile Medical Applications* final guidance document[3] if it meets the criteria of that policy.

For a product to qualify as a low risk general wellness device under this policy, it must be intended for only general wellness use (as defined below), and it must present a low risk to the

safety of users and other persons. Thus, to determine whether a product qualifies for FDA's policy under this guidance, one must evaluate both the risk and the intended use.

Is the Product Low Risk?

FDA provides three threshold questions for manufacturers to determine whether a general wellness product is low risk. They are:

1) Is the product invasive?[4]
2) Is the product implanted?
3) Does the product involve an intervention or technology that, absent special controls, may pose a risk to the safety of users and other persons?[5]

If the answer to any of these questions is yes, then the product is not considered low risk for the purposes of a general wellness device.[6] FDA additionally suggests evaluating whether a general wellness device is similar to any device already regulated by FDA and subject to special controls. If a similar product is regulated, then the device likely will not fall under FDA's general wellness device policy. The guidance document provides a list of specific examples of products that would not be considered low risk, including sun lamps, laser skin therapy, and products that puncture the skin and would increase risk of infection transmission.

Is the Intended Use General Wellness?

FDA delineates two types of general wellness uses:

1) An intended use that relates to maintaining or encouraging a general state of health or a healthy activity, or

2) An intended use that relates the role of a healthy lifestyle with helping to reduce the risk or impact of a certain chronic disease 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.

Maintaining General Health or Healthy Activity

The first category of general wellness intended uses may not reference any specific diseases or conditions, but may generally promote products for sustaining or improving functions associated with a general state of health, such as weight management, physical fitness, relaxation and stress management, mental acuity, self-esteem, sleep management, and sexual function. A longer list of specific illustrative examples of claims that fall within and outside of this intended use category can be found in the guidance document. Notably, FDA revised the examples from the draft guidance document to add "enhances learning capacity" as a permissible claim, eliminate "enhances cardiac

function," and clarify that treating anxiety disorders is outside of the claims permissible in this category.

Living Well with a Disease or Condition as Part of a Healthy Lifestyle

The second category is more nuanced. Claims falling under this part of the policy will surely be more scrutinized and should therefore be more carefully crafted. This category allows manufacturers to promote the product for more specific wellness in the context of a disease or condition, but only when it is "well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition." FDA expands upon this requirement in the guidance document to note that "the claim that the healthy lifestyle choice(s) may play an important role in health outcomes should be generally accepted." The associations between healthy lifestyle choices and the chronic disease or condition that are captured in the intended use, should be described either in peer-reviewed scientific publications or in official statements made by healthcare professional organizations, which include "associations and colleges such as American Medical Association (AMA), American heart association (AHA), American Association of Clinical Endocrinologists (AACE), American College of Rheumatology, etc."[7]

So long as these healthy lifestyle criteria are met, FDA provides for two subcategories of intended use that may reference chronic diseases or conditions:

i. Intended to promote, track, and encourage choice(s) which, as a part of a healthy lifestyle, may help to reduce the risk of certain chronic diseases or conditions, or
ii. Intended to promote, track, and encourage choice(s) which, as a part of a healthy lifestyle, may help living well with certain chronic diseases or conditions.

Examples of chronic diseases or conditions to which these intended uses could apply include heart disease, high blood pressure, type 2 diabetes, and anxiety disorders. As with the first category of intended uses, FDA provides a longer list of specific illustrative examples in the guidance document, but notably, FDA has included examples that reference migraine headaches and anxiety in the final guidance.

The examples provided in each category of intended use are an excellent starting point for crafting a new product's intended use, as well as the accompanying marketing materials. Any product advertising and marketing materials should not promote a product beyond the scope of its intended use and should be reviewed for conformance to the principles set forth in the final guidance document.

In addition to examples, the guidance document provides a decision tree to assist industry in determining whether a product falls within the scope of FDA's general wellness device policy.

Conclusion

FDA's flexible regulatory framework for general wellness devices is a welcome and common sense approach that will allow industry to expand in the wellness product marketplace with fewer hoops to jump through and less concern for surprise regulatory enforcement. Furthermore, on the heels of the *Mobile Medical Applications* final guidance document issued last year, the general wellness device policy continues a trend of enforcement discretion for low-risk products, which will free up agency resources to focus on more pressing regulatory concerns.

Finally, it is worth noting that while FDA will not regulate products in the general wellness space, the Federal Trade Commission (FTC) still maintains jurisdiction over the advertising of such devices. Under the Federal Trade Commission Act, FTC may take enforcement action against advertisers if advertising is unfair or deceptive, or if product claims are not adequately substantiated.

1. http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm429674.pdf.
2. Federal Food, Drug, and Cosmetic Act, Section 201(h).
3. http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf.
4. FDA defines a product as invasive if it penetrates or pierces the skin or mucous membranes of the body.
5. FDA provides lasers, radiation exposure, and electrical stimulation as examples.
6. FDA notes that this risk analysis is appropriate only for general wellness devices as described in this guidance document.
7. *General Wellness: Policy for Low Risk Devices – Guidance for Industry and Food and Drug Administration Staff* at 4, July 29, 2016, http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm429674.pdf.